UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year ended December 31, 2021

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 000-56257

ACCUSTEM SCIENCES, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**87-3774438**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
5 Penn Plaza, 19th Floor, #1954 New York, NY	**10001**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 00 44 2074952379

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ACUT	Over the Counter ("OTC")

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b 2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b 2 of the Exchange Act). Yes ☐ No ☒

The registrant completed the initial offering of its common stock on March 23, 2022. Accordingly, there was no public market for the registrant's common stock as of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter.

As of April 11, 2022, there were 11,337,102 shares of Common Stock, $0.001 par value outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND OTHER INFORMATION CONTAINED IN THIS REPORT

This Annual Report on Form 10-K (this "Annual Report") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy," "future," "likely" or the negative thereof or other variations thereon or other comparable terminology. All statements other than statements of historical facts included in this Annual Report regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements we make regarding: expectations for revenues, cash flows and financial performance and the anticipated results of our ongoing development and business strategies.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, but are not limited to, the following:

- the success, cost and timing of our clinical development of our products, including the progress of, and results from, our preclinical and
- clinical trials of StemPrintER and SPARE products, our discovery programs and other potential product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our ability to compete with companies currently marketing or engaged in the development of treatments for indications that our product candidates are designed to target;
- our plans to pursue research and development of other future product candidates;
- the potential advantages of our product candidates and those being developed;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- the success of our collaborations and partnerships with third parties;
- our estimates regarding the potential market opportunity for our product candidates;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for manufacture of our product candidates;
- our intellectual property position;
- our expectations related to the use of capital;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and future clinical trials;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations; and
- our competitive position.

The forward-looking statements are based upon management's beliefs and assumptions and are made as of the date of this report. We undertake no obligation to publicly update or revise any forward-looking statements included in this report. You should not place undue reliance on these forward-looking statements.

This report also contains or may contain estimates, projections and other information concerning our industry and our business, including data regarding the estimated size of our markets and their projected growth rates. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, studies and similar data prepared by third parties, industry and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

Unless otherwise stated or the context otherwise requires, the terms "AccuStem" "we," "us," "our" and the "Company" refer collectively to AccuStem and, where appropriate, its subsidiaries.

Item 1. Business

Company Overview

AccuStem Sciences, Inc.(the "Company") is a life sciences company focused on improving outcomes for patients with cancer. Our plan is to develop and commercialize a variety of products in the diagnostics, pharmaceutical and medical device spaces that enable more informed treatment planning and more effective treatment options for patients. Our initial approach will be the commercialization of a proprietary genomic platform, StemPrint, for recurrence risk stratification of different types of cancer. StemPrint was developed to measure the "stemness" of tumors, or how likely a cancer is to recur or be resistant to standard treatments, which could impact how patients are managed in oncology clinics. To augment this unique offering we also plan to provide ancillary commodity testing (e.g., hereditary genetic testing, somatic mutation testing) to provide additional information and value to our clients.

Our primary product candidate is StemPrintER, a 20-gene prognostic assay intended for the prediction of the risk of distant recurrence ("DR") in luminal, ER+/HER2-negative breast cancer patients. StemPrintER has been validated in several retrospective cohorts and studies, the largest of which are a consecutive series of approximately 2,400 patients from the European Institute of Oncology (IEO) and approximately 800 patients from the TransATAC study. These studies all confirm that StemPrintER is highly prognostic for outcomes in patients with breast cancer and indicate the potential utility of the test in the oncology clinic.

Company History and Acquisition

AccuStem Sciences Limited was created in connection with its demerger (spin-off) from Tiziana Life Sciences plc ("Tiziana") and the AccuStem Sciences Limited was incorporated in England and Wales on June 5, 2020 as a private company with limited liability under the Companies Act with indefinite life and company number 12647178. The demerger was conditional upon, among other things, court approval of a Tiziana capital reduction, which was approved by special resolution of Tiziana's shareholders on October 2, 2020. The court sanctioned the related Tiziana capital reduction on October 27, 2020, and the demerger became effective on October 30, 2020. We have re-registered as a public limited company if and when we may apply to have our shares traded on NASDAQ.

The demerger agreement provides for the transfer by Tiziana to us of the entire issued share capital of StemPrintER Sciences Limited ("StemPrintER"), the Tiziana entity to which Tiziana contributed all of the assets and intellectual property relating to the StemPrintER and SPARE projects and $1,353,373 (£1,000,000) in cash. The demerger consideration will be satisfied by the Company's allocation and issuance of the new shares directly to Tiziana's shareholders.

For the purposes of the demerger, Tiziana first transferred the assets relating to the StemPrintER project and the SPARE project (primarily the benefit of the license from IEO/University of Milan and an outsourced research program) to a separate company, StemPrintER, together with $1,353,373 (£1,000,000) in cash. As a result of this step, StemPrintER became an operating entity. In the next step, Tiziana transferred StemPrintER's shares to us in return for shares to Tiziana's shareholders, on a one for one basis, and Tiziana declared a dividend in specie to its shareholders of those shares.

The objective of the demerger was to maximize value to Tiziana's shareholders through the further commercialization of the StemPrintER project by transferring Tiziana's interest in the StemPrintER project assets and intellectual property. The separation of Tiziana's existing life sciences research and development related to the StemPrintER project into the Company will enable us and Tiziana to separately direct our respective business strategies to maximize value for our respective shareholders and other stakeholders. In addition, the separation of the StemPrintER project into a separate company is intended to enhance the visibility and transparency of our and Tiziana's respective businesses, provide choice and liquidity for all investors to choose to invest, or not, in the bioscience and diagnostics businesses, and provide clear accountability, together with targeted incentive arrangements, for management and employees. The demerger will allow the Company to focus these commercialization efforts as a separate company with reserves of $1,353,373 (£1,000,000) which was collected in January 2022.

Tiziana has and will continue to provide certain limited management and administrative services to the Company following the completion of the demerger. Tiziana and the Company have entered into a demerger agreement which sets out certain agreements that govern certain aspects of the relationship between Tiziana and the Company and their respective subsidiaries following the demerger, details of the demerger Agreement are more fully outlined in "Item 7 —Management Discussion & Analysis".

Our principal capital expenditures are devoted to conducting research and development of our novel product candidate, StemPrintER, establishing US corporate headquarters with a Clinical Laboratory Improvement Amendments "CLIA"-certified laboratory and further validating the StemPrint platform in other tumor types as further discussed in "Item 7—Management Discussion & Analysis".

On December 1, 2021 Accustem Sciences Inc., a Delaware corporation ("New Accustem"), has become the successor issuer to Accustem Sciences Limited, a public limited company incorporated in England and Wales ("Old Accustem"), pursuant to Rule 12g-3(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such succession occurred following the effectiveness, on December 1, 2021 (the "Effective Time"), of a United Kingdom court-approved scheme of arrangement (the "Scheme of Arrangement") in which (i) every 20 ordinary shares, £0.01 par value per share, of Old Accustem (the "Old Accustem Ordinary Shares") were exchanged for one share of common stock, $0.001 par value per share, of New Accustem (the "New Accustem Common Stock") and (ii) every 10 ADS representing two Old Accustem Ordinary Shares were exchanged for one New Accustem Common Stock, which resulted in New Accustem becoming the holding company of Old Accustem. On December 30, 2021, the Company completed dissolution of Old Accustem.

Emerging Growth Company Status

We qualify as an "emerging growth company" as defined in the U.S. Jumpstart Our Business Startups Act of 2012. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. This includes an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act. We may take advantage of this exemption for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than $1.07 billion in total annual gross revenue, have more than $700.0 million in market value of our common stock held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these provisions that allow for reduced reporting and other requirements.

StemPrintER and Market Opportunity in Breast Cancer

Each year, more than two million women are diagnosed with breast cancer worldwide. Endocrine receptor positive (ER+) breast cancers constitute the majority of breast cancer cases (~75%) and display remarkable variability in clinical behavior. This heterogeneity makes prognosis and therapy response often challenging to predict using the standard clinicopathological features of the tumor. Although the overall prognosis for this group of patients is good, a significant proportion (>20%) of these patients will experience distant recurrence in the first 10 years post-surgery. For ER+ patients who also have a negative HER2 status (HER2-), the standard of care is endocrine therapy with the addition of adjuvant chemotherapy in those patients considered to be at risk of recurrence according to clinicopathological parameters. However, it has become apparent that these parameters are often insufficient to predict risk of recurrence in ER+/HER2- breast cancer patients, and, as a consequence, a significant proportion of these patients are either over- or under-treated. We anticipate StemPrintER will be used in conjunction with clinical evaluation to identify a patient's risk of recurrence to help physicians optimize treatment planning throughout the care continuum.

StemPrintER has a novel biological basis in the stem cell biology and interrogates the intrinsic content and aggressiveness of cancer stem cells of the primary tumor. The assay uses a reliable real-time quantitative reverse transcription polymerase chain reaction (qRT-PCR), formalin-fixed, paraffin-embedded (FFPE) platform for testing. StemPrintER was developed and clinically validated in a retrospective analysis using a consecutive series of approximately 2,400 patients with breast cancer from the European Institute of Oncology (IEO). Subsequently, StemPrintER was independently validated using a cohort of approximately 800 ER+/HER2- postmenopausal patients from the prospective, randomized TransATAC trial.

StemPrintER Scientific Background

The development and validation of multi-gene assays that interrogate the underlying biology of tumors for accurate prognostication of individual cancer patients has represented an expanding area of research for more than a decade. The increasingly recognized relevance of cancer stem cells to tumor heterogeneity and disease course suggests that the knowledge of the "degree of stemness" of a breast cancer might substantially advance individualized patient management. StemPrintER was developed to be a novel genomic predictor of patient outcomes based on a cluster of 20 stem cell genes whose expression levels would be capable of stratifying patients into two distinct groups: those at very low risk of cancer recurrence and those at an increased risk of their cancer returning. This information is intended to inform treatment planning at various timepoints throughout the patient care continuum.

Our initial research focused on genes that could discriminate mammary stem cells from progeny cells in normal breast tissue. Only those genes that were expressed at higher levels in mammary stem cells versus progeny were selected. Selection criteria were based on the premise that cancer stem cells might display traits reminiscent of those present in normal mammary stem cells and, since cancer stem cells are rare, the selection of overexpressed genes (mammary stem cells versus progeny) afforded a higher likelihood of scoring differences, with respect to under-expressed genes.

Based on existing published research, several of the 20 stem cell genes display evident connection to metastatic dissemination through their role in matrix degradation, migration, invasion and engraftment (e.g., MMP1, SNF, MIEN1, PHLDA2, EPB41L5). For other genes in the signature (RACGAP1, H2AFZ, H2AFJ, APOBEC3B, CENPW, TOP2A CDK1) it was considered possible, or even probable, that they were significant in the establishment of cancer stem cell phenotypes and might be linked to involvement in genomic instability. A final set of genes, whose putative role in metastasis is less obvious, includes those involved in: (a) metabolism reprogramming and mitochondrial physiology (MRPS23, NDUFB10, Phb); (b) mRNA ribonucleoparticle biogenesis, mRNA transcription, splicing and export, and RNA processing and degradation events (ALYREF, EXOSC4); and (c) survival/escape from apoptosis, which is connected to resistance to hormonal and/or chemotherapy through hijacking of signalling pathways, such as TGF-beta and pi3k-AKT-mTOR (NOL3, LY6E, EIF4EBP1). Additional evidence for a mechanistic link between the 20 genes and the cancer stem cell phenotype comes from the observation that these genes are frequently overexpressed in breast cancer, sometimes as a consequence of gene amplification.

StemPrintER Clinical Research History

Through a validation study analyzing a large prospective, randomized cohort of breast cancer patients with high-quality follow-up, and a series of retrospective studies based on the use of fresh tumor samples and gene expression profiles from additional breast cancer patients, it has been established that StemPrintER predicts the individual likelihood of developing distant metastases in luminal (ER+/HER2-) and triple negative breast cancers. Of note, our genomic predictor comprises a set of genes that do not belong (with one exception) to any other genomic tool or molecular classifier described for triple negative or luminal breast cancers. We accordingly believe that the result of our research is the development of a unique tool capable of probing into the “degree of stemness”, and hence into the clinical outcome, of breast cancers.

The largest validation study for StemPrintER involved the retrospective analysis of nearly 2,400 breast tumor samples collected through the IEO clinical network. In this published study, StemPrint and StemPrintER were highly prognostic for early and late recurrences in luminal (ER+/HER2-) and triple negative (ER-/PR-/HER2-) breast cancer patients, independent of standard clinical characteristics.

In the TransATAC cohort of ER+/HER2- post-menopausal breast cancer patients, a team of scientists from the IEO conducted an independent validation of StemPrintER using banked study samples in collaboration with the Royal Marsden Hospital and Queen Mary University in London. The likelihood ratio x2 (LRx2) and Kaplan-Meier survival analyses were used to assess prognostic information provided by StemPrintER and OncotypeDX. Comparative analyses were made for DR risk over the entire 10-year follow-up period, as well as in the early (0-5 years) or late (5-10 years) interval. Our study results showed that StemPrintER was highly prognostic for recurrence risk (insert HR and stats). Additionally, StemPrintER outperformed Oncotype DX RS in 10-year DR risk prediction in all patients, as well as in N0 and N1-3 patients.

Commercialization of the StemPrint Platform and StemPrintER

From a clinical standpoint, although future studies are warranted to increase the level of clinical evidence of the reliability and applicability of the 20-gene test, the recent independent validation using the TransATAC cohort demonstrates the immediate relevance of StemPrintER for the clinical management of breast cancer patients, in particular for those with ER+/HER2- disease. These luminal patients represent the majority (~75%) of newly-diagnosed cases and display high molecular heterogeneity and variability in their clinical behavior. Accordingly, ER+/HER2- breast cancer patients can greatly benefit from accurate stratification of their risk of recurrence for the development of an optimal treatment plan.

Historically in breast cancer, multi-gene assays have been used to inform the role of systemic therapy following surgery. While we believe that StemPrintER may have the same ability, especially in identifying patients with excellent long-term prognosis who would not derive significant benefit from adjuvant chemotherapy, we plan to focus on answering alternative clinical questions not addressed by current commercially-available products. We will devote our resources to obtaining established cohorts of patients and running prospective clinical trials that may demonstrate a broader utility for StemPrintER.

Our initial plan is to launch StemPrintER testing for patients with breast cancer once we have achieved several key milestones. First, we are planning to build corporate headquarters in Phoenix, AZ that will also house a clinical laboratory. That laboratory will be responsible for processing, testing and reporting StemPrintER results for all commercial samples. Further, once the laboratory is established, we will obtain CLIA certification so that we are able to report results for clinical use and to seek reimbursement from the Centers for Medicare and Medicaid Services. Finally, we will transfer the StemPrintER technology from the laboratory in which it was developed (at the IEO) to our laboratory in Phoenix. Once those tasks are complete we will be able to commercially launch StemPrintER, and we plan to focus on the US market.

To augment the value proposition of the StemPrint platform, we also plan to offer additional “commodity” testing (e.g., IHC receptor testing, hereditary genetic testing). These additional tests should create significant value for our customers while leveraging existing laboratory equipment and processes for economy of scale and providing additional revenue opportunities to the Company.

Given the broad applicability of tumor “stemness”, which has been evaluated in a multitude of different cancers, we believe the StemPrint platform will have meaningful clinical utility beyond breast cancer. As such, we plan on validating and commercializing StemPrint in a variety of different tumor types. Each tumor type, where applicable, would also include ancillary testing to boost our value proposition to customers.

Reimbursement Strategy

Our revenue is expected to be derived from different sources including standard private third-party and government medical insurance coverage and reimbursement models. Prior to full commercial scaling, we expect to focus our sales efforts on a small number of early adopting sites to establish ordering history with payers, effective logistics and additional clinical utility, subject to successful validation trials and approvals under the CLIA certification or upon the obtaining of a CE mark for the test.

Competition

Genetic and genomic testing play an important and continually evolving role in the oncology space. In breast cancer, there are several companies that offer genomic testing that might be competitive with StemPrintER.

Breast Cancer Index (Hologic) is an assay that is designed to predict the likelihood of late breast cancer recurrence and determine the need for extended endocrine therapy (an additional 5 years of endocrine therapy beyond the standard five years). The test is for pre- and post-menopausal patients with ER+/HER2- disease and up to three positive lymph nodes.

EndoPredict (Myriad) is a CE-marked assay that is designed to predict the likelihood of metastases developing within 10 years of an initial breast cancer diagnosis. The test is for pre- and post-menopausal patients with early stage ER+/HER2- breast cancer and up to 3 positive lymph nodes.

MammaPrint (Agendia) is a Food and Drug Administration ("FDA")-cleared, CE-marked assay that is designed to assess the risk of distant recurrence within 5 years and whether a person would benefit from chemotherapy. The test is for pre- and post-menopausal patients with stage 1 or 2 breast cancer, with a tumor size of 5 centimeters or less, and LN-negative or LN-positive disease (up to 3 positive nodes). The test can be used irrespective of ER and HER2 status.

OncotypeDX is a CE-marked assay that is designed to asses the risk of distant metastasis and to predict the need for chemotherapy in patients with ER+/HER2- breast cancer. The test can be used in pre- and post-menopausal patients with up to three positive lymph nodes.

Prosigna (Veracyte) is a CE-marked assay designed to provide information on breast cancer subtype and to predict distant recurrence-free survival at 10 years. The test is for postmenopausal patients with early-stage ER+/HER2- breast cancer that is LN-negative or LN-positive (up to 3 positive nodes).

The "commodity" testing that we plan to offer (e.g., IHC receptor testing, somatic mutation testing, hereditary genetic testing) has numerous competitors in industry (e.g., Ambry, Color Health, Foundation Medicine, Guardant, Invitae, Laboratory Corporation of America, Natera, Neogenomics, Quest Diagnostics, Tempus) and academic and hospital settings.

Government Regulation

U.S. health regulatory overview

The following provides an overview of key aspects of laboratory service and medical device regulation within the U.S. It should be noted this overview does not address every facet of regulation at the federal and state level, but only those that would generally be most relevant to the activities described in this registration statement.

Federal and state clinical laboratory licensing requirements

The CLIA governs the operations of all clinical laboratories operating in or returning results to individuals in the U.S. CLIA is administered by The Centers for Medicare & Medicaid Services ('CMS'), in partnership with state health departments. A clinical laboratory is defined as a laboratory that performs testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the assessment of health. Clinical laboratories must hold a certificate applicable to the type of laboratory examinations they perform and must demonstrate compliance with regulations addressing, among other things, personnel qualification and training, record keeping, quality control, and proficiency testing, all of which are intended to ensure the timeliness, reliability, and accuracy of clinical laboratory testing services. CLIA requires that laboratories demonstrate or verify the analytical validity of all tests they perform. Where a clinical laboratory analyses specimens based on a proprietary test method (i.e., a laboratory developed test, 'LDT'), the laboratory must, among other things, document the accuracy, precision, specificity, sensitivity of, and establish a reference range for, such test.

CMS provides for exemption from CLIA for states that develop clinical laboratory standards that are at least as stringent as federal requirements. Both New York and Washington State are exempt from CLIA. The NYS Clinical Laboratory Evaluation Program requires all independent clinical laboratories operating in, or testing specimens from, NYS to obtain a laboratory permit prior to commencing operations, and all clinical laboratories performing LDTs to submit test validation documentation demonstrating the tests' analytical and clinical validity.

Failure to comply with CLIA certification and state clinical laboratory licensure requirements may result in a range of enforcement actions, including certificate or license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and revocation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity.

Food and Drug Administration

The FDA regulates, among other medical products, "medical devices" which include certain articles intended for use in the diagnosis, prevention, cure, mitigation, or treatment of disease or intended to effect the structure or function of the body. Whether a product is intended for use as a medical device is generally determined, in the first instance, based on the manufacturer's product labelling, which includes the label affixed to the product, materials distributed with the product, and promotional communications concerning the product.

Devices classified as Class I (low risk), generally may be marketed without FDA pre-market review, but are subject to "general controls", including establishment registration, device listing, record keeping, medical device reporting, and quality system regulations, including design controls. Devices classified as Class II (moderate risk), may, in addition to general controls, also be subject to "special controls" (e.g., performance standards / manufacturing standards, post-market surveillance, patient registries, special labelling requirements, pre-market data requirements and guidelines), and also generally must obtain 510(k) premarket clearance or DeNovo authorization from FDA. Class III (high risk) devices must, in addition to general controls, obtain FDA pre-market approval through the submission of a pre- market approval application that contains evidence, including data from adequate and well- controlled clinical studies, demonstrating that the device is safe and effective for its intended use. In general, devices that require FDA pre-market clearance or DeNovo authorization may not be commercially distributed or promoted prior to obtaining such authorization, although they may be distributed and used for the purpose of developing the clinical data necessary to support FDA marketing applications, subject to certain limitations. Post-market changes to a cleared / authorized or approved device also may be subject to prior review by FDA, depending on the scope of the change and its potential impact on device safety and effectiveness.

It should also be emphasized that this pre-market review process is only one facet of FDA's regulation. For example, FDA regulates product labelling, including promotional claims; the manufacturing of medical devices, including their design, under FDA quality system requirements; clinical trials with new or modified products; and post-market monitoring for, reporting of, and action related to, safety concerns. Failure to comply with applicable pre and post-market device requirements can result in a determination by FDA that a device is "adulterated" (Section 501) or "misbranded" (Section 502) in violation of the U.S. Federal Food, Drug, and Cosmetics Act. The statute provides for a number of penalties, including seizure, injunction, criminal, and civil monetary penalties, for the sale or distribution of adulterated or misbranded devices. In general, prior to undertaking enforcement action, FDA will notify a regulated entity of a violation or suspected 36 violation through a communication, such as a "Warning Letter" or "Untitled Letter". If FDA identifies violations during inspection of a manufacturer's facility, the agency will issue a Form 483 listing the identified violation and directing the manufacturer to make the necessary corrections.

FDA regulation of software

Commercially distributed software applications that meet the definition of a medical device may be subject to FDA pre-market authorization, depending on their classification and software function. These include both applications that are components of a hardware medical device and certain "standalone" software. In 2017, FDA issued final guidance adopting international principles established by the International Medical Device Regulators Forum for the clinical evaluation of software as a medical device ("SaMD"), which refers to software that is intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. In 2019, FDA issued a guidance that provides guidance on FDA's oversight of device software functions including mobile medical apps that meet the definition of a device. While the guidance is not binding on either FDA or regulated industry, FDA intends to consider the principles in developing regulatory approaches for SaMD as well as for digital health technologies.

FDA regulation of LDTs

FDA regulates a category of medical devices, called in vitro diagnostic medical devices, or IVDs, that are used in the collection, preparation, and examination of specimens from the human body. IVDs include reagents, instruments, and systems that are intended for use in diagnosis of disease or other conditions, including the state of health, in order to cure, mitigate, treat, or prevention disease or its sequelae. FDA historically has taken the position that tests developed in-house by a clinical laboratory and used to analyze patient specimens meet the definition of an IVD and fall within the agency's regulatory jurisdiction. At the same time, FDA historically has for the most part exercised "enforcement discretion," i.e., has not required clinical laboratories performing LDTs to comply with IVD device requirements. In the past, FDA has signaled intent to modify its enforcement discretion policy with regard to LDT regulation, and in 2014 proposed a regulatory framework for LDTs, which it abandoned before implementation in 2016. As of August 19, 2020, the U.S. Department of Health and Human Services (HHS) determined that LDTs will not require a premarket review with FDA, but rather an applicant may voluntarily submit a premarket notification or premarket approval (or an Emergency Use Authorization in the case of COVID-19 tests) for their LDT. It is possible that Congress will enact legislation directing FDA to regulate LDTs.

The U.S. Federal Trade Commission and Consumer Protection Laws

Within the U.S., the U.S. Federal Trade Commission ("FTC"), has authority to regulate advertising for most medical devices and for laboratory services. In addition, various state consumer protection laws exist which can similarly regulate claims that are being made by entities with respect to what benefits their products or services can provide to consumers. In some instances, FTC or U.S. states have taken action with respect to medical products based on claims being made with respect to, e.g., their benefits to patients, seeking various penalties, such as injunctions and substantial fines. Activities have focused more, to date, on products that are sold directly to consumers, such as dietary supplements, as opposed to prescription products ordered by physicians, although the possibility exists that FTC or other consumer protection bodies could take steps to regulate claims with respect to IVDs or LDTs.

Fraud and Abuse

The significant U.S. fraud and abuse laws include the:

- Anti-Kickback Statute: the federal U.S. Anti-Kickback Statute (42 U.S. Code § 1320a–7b(b) imposes criminal penalties on persons and entities for, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease or order of a good, facility, item or service for which payment may be made under a government healthcare program such as Medicare and Medicaid.

- False Claims Act: the U.S. federal false claims and civil monetary penalties laws, including the federal civil U.S. False Claims Act (31 USC. §§ 3729 – 3733), impose criminal and civil penalties, including through civil whistleblower or qui tam actions against individuals or entities for, among other things knowingly presenting or False Claims Act: the U.S. federal false claims and civil monetary penalties laws, including the federal civil U.S. False Claims Act (31 USC. §§ 3729 – 3733), impose criminal and civil penalties, including through civil whistleblower or qui tam actions against individuals or entities for, among other things knowingly presenting or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages, significant per-claim penalties, and administrative penalties.

Transparency requirements

The U.S. Physician Payments Sunshine Act (known as Affordable Care Act Section 6002: Transparency Reports and Reporting of Physician Ownership or Investment Interests) requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments or transfers of value made to physicians and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Any failure to report or providing incomplete or misleading information may subject the Company to penalties. Analogous state laws. Analogous state fraud and abuse laws and regulations, such as U.S. state antikickback and false claims laws, can apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by governmental or non-governmental third-party payors. These laws are generally broad and are enforced by many different U.S. federal and state agencies as well as through private actions. Some state laws require adherence to compliance guidelines promulgated by the U.S. federal government and require device and drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Data privacy and security

Health Insurance Portability and Accountability Act of 1996 ("HIPAA")

The HIPAA imposes criminal and civil liability for, among other things, failing to protect the privacy of patient and security of patient data. Additionally, the HIPAA by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations on covered entities and their business associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf, including mandatory contractual terms as well as implementing reasonable and appropriate administrative, physical and technical safeguards with respect to maintaining the privacy, security and transmission of protected health information.

Federal Trade Commission ("FTC")

The FTC has taken an active role with regard to protection of personal information, relying on its broad consumer protection powers to seek substantial penalties where companies that have made deceptive or misleading statements regarding practices of collecting and safeguarding data or did not have adequate safeguards to protect information consistent with their claims regarding data security. State laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Intellectual Property

Our intellectual property portfolio comprises the following patents:

We have rights to a patent family that discloses methods and kits for stratifying risk in breast cancer patients, licensed from IEO/University of Milan. This patent family includes pending applications in Canada and the United States and an allowed application in Europe. Patents issued in family will expire in June 2037, excluding any patent term extensions available in several jurisdictions.

We have rights to a second patent family that discloses methods and kits for determining the risk of breast cancer recurrence, licensed from IEO/University of Milan. This patent family includes one pending application in Europe. Patents issued in this family will expire in May 2041, excluding any patent term extensions available in several jurisdictions.

We are not aware of any third-party claims or contested proceedings in relation to our intellectual property portfolio.

Legal Proceedings

We are not party to any material legal matters or claims. In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

Human Capital

As of December 31, 2021, the Company had 1 full time employee. In the first quarter of 2022, 2 additional full time employees joined the Company. These employee are not represented by a labor union or covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

Compensation, Benefits, and Development

We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, and a robust employment package that promotes well-being across all aspects of our employees' lives, including health care and paid time off.

Diversity and Inclusion

We value the diversity of our employees and take pride in our commitment to diversity and inclusion across all levels of our organizational structure and with respect to our board of directors. We continue to focus on expanding our commitment to diversity and inclusion across our entire workforce, including working with managers to develop strategies for building diverse teams and promoting the advancement of employees from diverse backgrounds.

CORPORATE INFORMATION

The Company's legal name is AccuStem Sciences, Inc. Our registered office is situated at 5 Penn Plaza, 19th Floor, #1954 New York, NY, and our telephone number is +44 (0) 20 7495 2379. We have one wholly owned subsidiary: StemPrintER Sciences Limited, a private company incorporated in England and Wales with limited liability under the Companies Act. Our website address is www.accustem.com. The reference to our website is an inactive textual reference only and information contained in, or that can be accessed through, our website or any other website cited in this registration statement is not part of hereof.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission ("SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The SEC maintains an internet website, www.sec.gov, that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC.

Copies of each of our filings with the SEC on Form 10-K, Form 10-Q, and Form 8-K and all amendments to those reports, can be viewed and downloaded free of charge at our website, www.accustem.com, as soon as reasonably practicable after the reports and amendments are electronically filed with or furnished to the SEC.

Our code of ethics, other corporate policies and procedures, and the charters of our Audit Committee, Compensation Committee, and Nominating/Corporate Governance Committee are available through our website at www.accustem.com.

Item 1A. Risk Factors

The following risk factors may be important to understanding any statement in this Annual Report on Form 10-K or elsewhere. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations and stock price.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in this section below, that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in more detail in the risk factors below, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. Such risks include, but are not limited to:

Risks Specific to the Development of the Business

We do not have collaborations in place with institutions for utility studies and there is no guarantee that we will be able to demonstrate prospective clinical utility of the StemPrintER and SPARE products.

Following the completion of the initial retrospective validation studies in two independent cohorts in respect of the StemPrinter and SPARE products, we are likely to run clinical utility studies to support applications for reimbursement, which are necessary for successful commercialization and to provide further evidence to support marketing claims. We have not yet identified which institutions will carry out the utility studies and have not yet entered into the relevant agreements with these institutions. There is a risk that we will not be able to secure these collaborations, which would impact our ability to proceed to the utility study stage. Whilst the utility studies are not a source of continuing revenue, such studies do provide a short-term revenue stream from sales of the tests run on the StemPrintER and SPARE products.

Furthermore, we may not be able to demonstrate the clinical utility of the StemPrintER and SPARE products in a real-world setting, which would impact our ability to secure reimbursement. If such reimbursement is not achieved, it will make commercialization of the StemPrintER and SPARE products significantly more challenging and would impact our ability to generate revenue and, accordingly, result in a material adverse impact on our business, financial condition and results of operations and those of our wholly-owned subsidiary, StemPrintER Sciences Limited (which we refer to collectively as the "Group").

There are risks associated with the process of establishing a U.S. Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified laboratory and in offering StemPrintER and SPARE products as laboratory developed tests ("LDTs") which are outside our control.

The StemPrintER and SPARE products do not as yet have status as LDTs and we do not yet have a CLIA-certified laboratory.

Even if we eventually obtain the required FDA clearance and certification as LDTs for our products and proceed to commercialization, there are inherent risks associated with offering the StemPrintER and SPARE products as LDTs that are outside our control, including test uptake, which would have an impact on the amount of revenue we could generate. Further, we may not be able to generate the revenue amounts that we anticipate, if any, from offering the StemPrintER and SPARE products as LDTs.

We are dependent on other third parties who provide certain resources and services to us, as we have limited resources in the short-term

We rely in part on external resources to conduct the research, development, supply of supplies and clinical testing of our StemPrintER and SPARE products, including in relation to our laboratory systems which rely on software developed by external manufacturers. The future development of the StemPrintER and SPARE products and other products will partly depend upon the performance of these third parties. We cannot guarantee that the relevant third parties will be able to carry out their obligations under the relevant arrangements. In the future, we may depend on external resources in marketing, sales and distribution of its products. We cannot guarantee that we will be able to assign competent partners to conduct these tasks or that these tasks can be completed on the basis of terms which are beneficial to us. Additionally, while management is responsible for making decisions on our behalf, management will rely to a certain extent on the advice of external professional advisors. There is no guarantee that we will receive the correct advice from such advisors.

Disagreements between us and any third parties could lead to delays in our research and development ("R&D") program and/or commercialization plans. If any third parties were to terminate their relationships with us, we would be required to obtain development and/or commercialization services from other third parties or develop the relevant functions internally, which could have an adverse effect on our business, results of operations and financial condition.

We are subject to research and product development risk

We may not be able to develop new products or to identify specific market needs that can be addressed by tests or solutions developed us. Product development will be a key ongoing activity for us. However, there can be no assurance that further products will be developed, successfully launched, or accepted by the market. All new product development has an inherent level of risk and can be a lengthy process and suffer unforeseen delays, cost overruns and setbacks, such as difficultly recruiting patients into clinical trials. The nature of the medical device industry may mean new products may become obsolete as a result of competition or regulatory changes which could have a material adverse effect on our business, results of operations and financial condition.

In addition, R&D may be subject to various requirements, such as research subject protection for individuals participating in clinical evaluations of new products, institutional review board oversight, regulatory authorizations, and design control requirements. Failure to comply with requirements could result in penalties, delay, or prevent commercialization of products.

We are subject to risks associated with medical and technological change and obsolescence

Demand for our products could be adversely impacted by the development of alternative technology and alternative medicines. There can be no assurance that the technology and products currently being developed by us will not be rendered obsolete. As a result, there is the possibility that new technology or products may be superior to, or render obsolete, the technology and products that we are currently developing. Any failure of ours to ensure that our products remain up to date with the latest advances may have a material adverse impact on our competitiveness and financial performance. Our success will depend, in part, on our ability to develop and adapt to these technological changes and industry trends and failure to do so could have a material adverse effect on our business, results of operations and financial condition.

Risks Relating to Intellectual Property

Our rights to develop and commercialize our product candidates are subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are reliant upon licenses and sublicenses from Istituto Europeo di Oncologia, Fondazione FIRC per l'Oncologia Molecolare and the University of Milan ("IEO/University of Milan") to certain patent rights and proprietary technology that are important or necessary to the development of our technology and product candidates, including the patents and know-how relating to manufacture.

On June 24, 2014, Tiziana entered into an exclusive licence agreement with IEO/University of Milan (the "License"), pursuant to which it obtained a worldwide, royalty-bearing, exclusive licence under certain patents and a worldwide, royalty-bearing, non-exclusive licence under certain know-how, respectively, of IEO/University of Milan to develop and commercialize licensed products in connection with a multi-gene prognostic tool. The License was assigned to us as part of the arrangements contained in the demerger agreement on October 30, 2020. Pursuant to the terms of the License, we are obliged to use commercially reasonable efforts in connection with the development and commercialization of the licensed products, including in accordance with specified diligence milestones. If we fail to meet our obligations under the License or if the License is terminated for any reason, it could negatively impact our business and strategic goals. The License may also be terminated for other reasons including breach and insolvency.

IEO/University of Milan have not provided the level of assurances and representations that are usually expected of similar options or licences, and generally the rights are granted on an 'as is' basis. Although it is appreciated that as an academic institution IEO/University of Milan is not in the habit of providing warranties, but generally it does leave us commercially exposed. Furthermore, our liability under the License is not capped.

If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of our patent protection is not sufficiently broad, our competitors could develop and commercialize similar products and technology

Our success depends, in large part, on our ability to seek, obtain and maintain patent protection in the United States, U.K. and other countries with respect to our product candidates and technology. Our licensors have sought, and we intend to seek, to protect our proprietary position by filing patent applications in the United States, the U.K. and elsewhere, related to certain technologies and our product candidates, StemPrintER and SPARE, that are important to our business.

Our current patent portfolio contains a limited number of patent applications, which are in-licensed from third parties. If we are unable to assert any such patents to prevent others from reproducing our technology and product candidates, or are unable to identify patentable aspects of our R&D output before it is too late to obtain patent protection, failure to do so could have a material adverse effect on our business, results of operations and financial condition.

Our intellectual property is open to challenge

No assurance can be given that any current or future trademark, design right or patent applications will result in registered trademarks, design rights or patents, that the scope of any patent, design or trademark protection or the protection provided by copyright or database rights or the right to bring actions for breach of confidentiality will exclude competitors or provide competitive advantages to us, that any of our owned or licensed-in patents, design rights or trademarks will be held valid if challenged or that third parties will not claim rights or ownership of the patents, design rights, trademarks or other intellectual property rights held by us.

If we cannot successfully enforce our intellectual property rights, this could have a material adverse effect on our business, financial condition and prospects. We may be subject to claims in relation to the infringement of patents, design rights, trademarks or other intellectual property rights owned by third parties. Adverse judgments against us may give rise to significant liabilities in monetary damages, legal fees and/or an inability to manufacture, market or sell products either at all or in particular territories.

Our strategy involves generating commercially valuable intellectual property that can be protected

We intend to augment our intellectual property portfolio. No assurance can be given that any future patent applications will result in granted patents, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of our patents will be held valid if challenged or that third parties will not claim rights in or ownership of the patents and other proprietary rights held by us. Should we fail to successfully obtain additional patent protection in respect its technology and products could have a material adverse effect on our business, results of operations and financial condition.

Market and Competitive Risks

We operate in a competitive market and may face competition from competitors involved in multi-gene prognostic assay for the prediction of risk of recurrence in luminal ER+/HER2- breast cancer patients

We may face competition from competitors involved in developing a multi-gene prognostic assay for the prediction of risk of recurrence in luminal ER+/HER2- breast cancer patients. Some of our competitors may have access to greater research, development, marketing, financial and personnel resources which may provide commercial advantages to those competitors. New products may be more effective, cheaper or more effectively marketed than StemPrintER and SPARE. A substantial increase in competition for any of these reasons could require us to, for example, increase our marketing or capital expenditure or require us to change our business model to remain competitive, which may have an adverse impact on our business including our profitability and/or financial condition.

The market opportunities for our product candidates may be smaller than we anticipate

We are focusing our R&D efforts on a multi-gene prognostic tool for predicting the recurrence of certain breast cancers. Our understanding of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from our prognostic assay, is based on estimates. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States, the United Kingdom ("U.K.", the European Union ("EU") and elsewhere may turn out to be lower than expected, may not be otherwise amenable to assessment with our product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

Further, there are several factors that could contribute to making the actual number of patients who receive our potential products, if and when approved, less than the potentially addressable market, such as the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

The future commercial success of our product candidates will depend upon the degree of each product candidates' market acceptance by physicians, patients, third-party payors and others in the medical community

We have no product authorized for marketing; our product candidates are at the validation study stage of development, and we may never have a product that is commercially successful. The commercial success of our product candidates will depend, in part, on their acceptance by physicians, patients and third-party payors as medically necessary, cost-effective and safe. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. Even if some product candidates achieve market acceptance, the market may not prove to be large enough to generate significant revenues. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including, but not limited to:

- the effectiveness and safety of our product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of our product candidates over alternative prognostic tools;
- the availability and cost of use relative to alternative prognostic tools;
- changes in the standard of care for the targeted indications for any product candidate;
- the willingness of physicians to use, and the target patient population to try, new prognostic tools;
- product labelling or product insert requirements of the FDA, the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA"), the European Medicines Agency ("EMA") or other regulatory authorities, including any limitations or warnings contained in a product's approved labelling;
- the timing of market introduction of competitive products;
- sales, distribution and marketing support;
- publicity concerning our product candidates or competing products and treatments;
- potential product liability claims;
- any restrictions on the use of our products together with other medications; and
- favourable third-party payor coverage and adequate reimbursement.

Even if a potential product displays favourable clinical properties and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our approved product candidates could limit our ability to market those products

We expect that coverage and adequate reimbursement by government and private payors will be essential for most patients to be able to afford our approved product candidates. Accordingly, sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under our health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

Market acceptance and sales of our products will depend significantly on the availability of adequate coverage and reimbursement from third-party payors and may be affected by existing and future healthcare reform measures.

Regulatory Risks

Our failure to maintain compliance of its future clinical laboratory operations with applicable laws could result in substantial civil or criminal penalties

The operation of a clinical laboratory by us will be in a highly regulated environment which, among other things, will require maintaining compliance with CLIA certification and state clinical laboratory licensing requirements. Failure to maintain compliance with these requirements may result in a range of enforcement actions, including certificate or license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties and criminal sanctions. Such failure may also result in significant adverse publicity. Any of these consequences could limit or entirely prevent our continued operation and therefore impact our financial performance.

We are subject to various health regulatory laws pertaining to fraud and abuse and related matters, and any failure to comply with such laws could result in substantial civil or criminal penalties

Our employees, independent contractors, consultants, and collaborators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our operations and reputation. We are exposed to the risk that our employees, independent contractors, consultants, and collaborators may engage in fraud or other misconduct to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we will take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws, standards or regulations. If any such actions are instituted against us, or our key employees, independent contractors, consultants, or collaborators, and we are not successful in defending ourself or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations.

Our failure to prevent a data breach would result in serious reputational damage to us and may result in civil or criminal lawsuits and associated penalties

We take our responsibility to maintain patient confidentiality and protect patient data extremely seriously. By its nature, the de-identified data that is being processed is highly sensitive and includes genetic and demographic information, the processing of which is subject to the most onerous obligations of applicable data protection legislation. If, due to a technical oversight, human error or malicious action by an employee or third party, the privacy, security or integrity of the data were compromised, we may be obliged to report such breach once we became aware of it under applicable laws and regulations such as HIPAA, General Data Protection Regulation ("GDPR"), Data Protection Act ("DPA") 2018 or other U.S. state, U.K. or EU member state specific laws as well as the data privacy laws of other countries such as Japan, Singapore, Hong Kong and China. Depending on the nature and extent of the breach, we may become subject to a regulatory investigation, which would divert time and financial resources from the day-to-day operation of the business and may result in civil or criminal lawsuits and financial fines and penalties as well as adverse publicity. If third parties and/or customers of ours become aware of such breaches, they may opt to cancel existing contracts or not enter new contracts with us, reducing revenue. We may also be required to personally inform the patients whose data was released or accessed as a result of a data breach, which may increase the severity of the reputational damage and may lead to patients revoking their consent for the data to be used by us. In addition, patients may have the right to bring claims for compensation for such breaches which might be brought by way of class or representative actions and claim significant sums as damages. To mitigate the risk of a data breach or related issue, we will employ technical security measures to protect data and work closely with our data providers to ensure that each party understands its obligations to protect personal data.

Risks Specific to our Current Size and Headcount

We are reliant upon the expertise and continued service of a small number of key individuals of our management, Board of Directors and scientific advisors

We rely on the expertise and experience of a small number of key individuals of its management, Directors and scientific advisors to continue to develop and manage our business. The retention of their services cannot be guaranteed. Accordingly, the departure of these key individuals could have a negative impact on our operations, financial condition, our ability to execute our business strategy and future prospects.

Going forwards, we will rely, in part, on the recruitment of appropriately qualified personnel, including personnel with a high level of scientific and technical expertise in the industry. We may be unable to find a sufficient number of appropriately highly trained individuals to satisfy its growth rate which could affects its ability to develop products as planned.

In addition, if we fail to succeed in pre-clinical or clinical studies, it may make it more challenging to recruit and retain appropriately qualified personnel. Our inability to recruit key personnel or the loss of the services of key personnel or consultants may impede the progress of our R&D objectives as well as the commercialization of our lead and other products, which could have a material adverse effect on our business, results of operations and financial condition.

We will need to expand our organization and may experience difficulties in managing this growth, which could disrupt our operations

As we mature, we expect to expand our full-time employee base and to hire more scientists, technicians and other skilled or experienced personnel. The management may need to divert a disproportionate amount of its attention away from the day-to-day activities and devote a substantial amount of time toward managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional products or technologies. If the management is unable to effectively manage our growth, our expenses may increase more than expected, the ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize products and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Specific to Our Financial Position and the Future Financing of the Business

We have incurred net losses in every year since our inception. We anticipate that we will continue to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical stage biotechnology company with a limited operating history. Since our inception in May 2013, we have incurred significant net losses. Our net losses were $670,614 and $54,248 for the year ended December 31, 2021, and for the period June 5, 2020 (date of inception) through December 31, 2020. As of December 31, 2021, we had an accumulated loss of 724,862. We expect that it could be several years, if ever, before we have a commercialized product candidate. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our shareholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- manufacture our product candidates in accordance with current good manufacturing practices, or "cGMP", for clinical trials or potential commercial sales;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- identify, assess, and acquire or in-license other product candidates and technologies;
- secure, maintain or obtain freedom to operate for any in-licensed technologies and products;
- address any competing technological and market developments; and
- expand our operations in the United States and Europe.

We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our R&D efforts, expand our business or continue our operations.

We need substantial additional funding to complete the development of its product candidates, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development, research operations or future commercialization efforts, if any

Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the R&D of, initiate further clinical trials of and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to product sales, marketing, manufacturing and distribution.

Furthermore, we expect to incur additional costs associated with operating as a public reporting company in the United States.

If we are unable to obtain adequate funding on a timely basis, we may be required to significantly curtail, delay or discontinue our R&D programs of our product candidates or any future commercialization efforts, be unable to expand our operations or be unable to otherwise capitalize on our business opportunities, as desired, which could harm our business and potentially cause a discontinuation of operations.

We may need to raise additional funding to take advantage of future opportunities

We may need to raise additional funding to take advantage of future opportunities. Such additional funding may not be available or, if available, may not be on terms that are favorable to us or our shareholders. If we are unable to obtain additional funding as required, we may be required to reduce the scope of our operations or anticipated expansion.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our consolidated financial statements as of December 31, 2021 were prepared under the assumption that we will continue as a going concern for the next twelve months. Due to our recurring losses from operations, we concluded that there is substantial doubt in our ability to continue as a going concern within one year after the financial statements are issued without additional capital becoming available. Our independent registered public accounting firm has issued an audit opinion that included an explanatory paragraph referring to our projected future losses along with recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional financial support from related parties or through additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Risks Related to our Business Operations

Risks relating to managing growth, employee matters and other risks relating to our business

Growth may place significant demands on our management and resources. We expect to experience growth in the number of our employees and the scope of our operations in connection with the continued development and, in due course, the potential commercialization of our products.

This potential growth will place a significant strain on our management and operations, and we may have difficulty managing this future potential growth.

We are highly dependent on our current Directors and the Senior Management and their services are critical to the successful implementation of our product development and regulatory strategies.

Challenges in identifying and retaining key personnel could impair our ability to conduct and grow our operations effectively

Our ability to compete in the highly competitive medical device industry depends upon our ability to attract and retain highly qualified management and sales teams. We are intending to recruit our own commercial team and expand our existing central infrastructure team. Many of the other pharmaceutical companies and academic institutions that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than it does. We might not be able to attract or retain these key persons on conditions that are economically acceptable. Our inability to attract and retain these key persons could have a material adverse effect on our business, prospects, financial conditions and results of operation.

We may become subject to product liability claims

We face an inherent risk of product liability and associated adverse publicity as a result of the clinical testing of our products and sales of our products once marketing approval is received from relevant regulatory authorities.

Criminal or civil proceedings might be filed against us by study subjects, patients, relevant regulatory authorities, pharmaceutical companies, and any other third party using or marketing our products. Any such product liability claims may include allegations of defects in manufacturing or design, negligence, strict liability, a breach of warranties and a failure to warn of dangers inherent in the product.

If we cannot successfully defend ourself against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products, if approved. Even if we successfully defends ourself against such product liability claims it could require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical study participants or difficulties in recruiting new study participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- diversion of management’s time and our resources;
- substantial monetary awards to patients, study participants or subjects;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- loss of revenues from product sales; or
- the inability to commercialize any our products, if approved.

Although we will maintain levels of insurance customary for our sector to cover our current and future business operations, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. In such cases, we would have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

If we or our partners, licensees and subcontractors were unable to obtain and maintain appropriate insurance coverage at an acceptable cost, or to protect ourself or themselves in any way against actions for damages, this would seriously affect the marketing of our products and, more generally, be detrimental to our business, prospects, results of operations or financial condition.

The ongoing COVID-19 pandemic and actions taken in response to it may result in disruptions to our business operations, which would have a materially adverse effect on our business, financial position, operating results, and cash flows.

In December 2019, the strain of coronavirus, SARS-CoV-2, causing the disease known as COVID-19, was reported to have surfaced in Wuhan, China. In March 2020, the WHO declared the COVID-19 outbreak a global pandemic. Since being discovered, new variants of SARS-CoV-2 have emerged.

Moreover, we may experience additional disruptions that could severely impact our business and development activities, including, but not limited to, strain on our suppliers and other third parties, possibly resulting in supply disruptions of our product candidates for preclinical development and potential future clinical trials we expect to initiate, decrease in clinical enrollment in any clinical trials we initiate, and the ability to raise capital when needed on acceptable terms, if at all. The COVID-19 pandemic continues to impact the global supply chain, causing disruptions to service providers, logistics, and the flow and availability of supplies and products. Disruptions in our operations or supply chain, whether as a result of government intervention, restricted travel, quarantine requirements, or otherwise, could negatively impact our ability to proceed with our clinical trials, preclinical development, and other activities and delay our ability to receive product approval and generate revenue.

In addition, the continued spread of COVID-19 may lead to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets. It is possible that the continued spread of COVID-19 could cause an economic slowdown or recession or cause other unpredictable events, each of which could adversely affect our business, results of operations, or financial condition.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. The extent to which COVID-19 impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19, the emergence of any new mutations or variants of the virus, the duration of the outbreak, travel restrictions imposed by the United States, Canada, India, and other countries, business closures or business disruption in the United States, Canada, India, and other countries, and the actions taken throughout the world, including in our markets, to contain COVID-19 or treat its impact. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our preclinical development efforts, healthcare systems, or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party Contract Research Organiztions ("CROs"), to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. In engaging these third parties, we typically have to, and expect to have to, negotiate budgets and contracts, which may result in delays to our development timelines and increases costs. Additionally, there is a limited number of qualified third-party service providers that specialize or have the expertise required to achieve our business objectives, and so it may be challenging to find alternative investigators or CROs, or do so on commercially reasonable terms. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with Good Clinical Practice ('GCP') requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we fail to exercise adequate oversight over any of our CROs or if we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon a regulatory inspection of us or our CROs or other third parties performing services in connection with our clinical trials, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates. These investigators and CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which increases the risk that a competitor will discover them or that this information will be misappropriated or disclosed.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and commercial prospects would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Repeating clinical trials or switching or engaging additional CROs involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a clinical trial has to be repeated or when a new CRO commences work. As a result, delays could occur, which could materially impact our ability to meet our desired clinical development timelines.

We expect to utilize, third parties to conduct our product manufacturing for the foreseeable future, and these third parties may not perform satisfactorily.

We may rely on CMOs for the manufacturing of our product candidates. If our future third-party manufacturers, do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, or if there are disagreements between us and our CMOs or any future third-party manufacturers, we will not be able to complete, or may be delayed in completing, the preclinical studies required to support future investigational new drug, or ("IND"), submissions and the clinical trials required for approval of our product candidates.

In addition to our current CMOs, we may rely on additional third parties to manufacture ingredients of our product candidates in the future and to perform quality testing, and reliance on these third parties entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- reduced control for certain aspects of manufacturing activities;
- termination or nonrenewal of manufacturing and service agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider.

Any of these events could lead to delays or failure to obtain regulatory approval or impact our ability to successfully commercialize any of our product candidates. Some of these events could be the basis for FDA, EMA or other regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

Risks Related to Our Common Stock

Further issuances of Common Shares may be dilutive

We may decide to offer additional shares in the future for capital raising or other purposes. Shareholders who do not take up or who are not eligible to take such an offer will find their proportionate ownership and voting interests in us to be reduced. An additional offering could also have a material adverse effect on the market price of the Common Shares as a whole.

Economic conditions and current economic weakness

Any economic downturn either globally or locally in any area in which we operate may have an adverse effect on the demand for our services. A more prolonged economic downturn may restrict our ability to generate a profit.

In addition, although signs of economic recovery have been perceptible in certain countries, the sustainability of a global economic upturn is not yet assured. If economic conditions remain uncertain this might have an adverse impact on our operations and business results.

Our ability to pay dividends in the future is not certain

We cannot guarantee that we will have sufficient cash resources to pay dividends in the future. The declaration, payment and amount of any future dividends are subject to the shareholders' discretion, or in the case of interim dividends, the Board's discretion, and will depend upon our earnings, financial position, cash requirements, availability or profits, any dividends and profits that we receive from our subsidiary companies, as well as provisions for relevant laws or generally accepted accounting principles from time to time.

Our principal shareholder has a significant holding in the company which may give them influence in certain matters requiring approval by shareholders, including approval of significant corporate transactions in certain circumstances

As of December 31, 2021, Gabriele Cerrone and Planwise Group Limited, a company in which Mr. Cerrone is the sole beneficial owner, held a beneficial ownership right (through his allotment of our shares as a Tiziana shareholder upon their issue and distribution following the effective date of this registration statement) in aggregate of approximately 37.12%. of our common stock. Accordingly, Mr. Cerrone and Planwise Group Limited may, as a practical matter, be able to influence certain matters requiring approval by shareholders, including approval of significant corporate transactions in certain circumstances. Such concentration of ownership may also have the effect of delaying or preventing any future proposed change in control of the Company. The trading price of the common stock, could be adversely affected if potential new investors are disinclined to invest in us because they perceive disadvantages to a large shareholding being concentrated in the hands of a single shareholder.

We are an "emerging growth company", and there are reduced disclosure requirements applicable to emerging growth companies

We are an "emerging growth company" as defined in the SEC's rules and regulations and we will remain an emerging growth company until the earlier to occur of (1) the last day of 2025, (2) the last day of the fiscal year in which we have total annual gross revenues of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer", under the SEC's rules, which means the market value of our equity securities that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

● not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;

● not being required to comply with any requirement that has or may be adopted by the Public Company Accounting Oversight Board (PCAOB) regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

● being permitted to provide only two years of audited financial statements in this initial registration statement, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

● reduced disclosure obligations regarding executive compensation; and

● an exemption from the requirement to seek nonbinding advisory votes on executive compensation or golden parachute arrangements.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this registration statement. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are considering whether we will take advantage of the extended transition period for complying with new or revised accounting standards. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

We will incur increased costs as a result of operating as a U.S. public company, and our management will be required to devote substantial time to new compliance initiatives

As a U.S. public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we will not incur as a private company.. In addition, the Sarbanes-Oxley Act of 2002, and rules subsequently implemented by the SEC have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk we will not be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we are unable to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause you to lose confidence in our reported financial information.

Our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

We have been a private company with limited accounting personnel to adequately execute our accounting processes and limited supervisory resources with which to address our internal control over financial reporting. As a newly public company, we have designed a control environment as required of public companies under the rules and regulations of the SEC. The Company identified a material weakness as of December 31, 2021 over internal controls over financial reporting due to a lack of accounting resources. If we fail to remediate a material weakness, or if we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders

Recently enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"), adopting elements of a territorial tax system, imposing a one-time transition tax, or repatriation tax, on all undistributed earnings and profits of certain U.S.- owned foreign corporations, revising the rules governing net operating losses and the rules governing foreign tax credits, and introducing new anti-base erosion provisions. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. Furthermore, it is also possible that there will be technical corrections or other legislation proposed with respect to the tax reform legislation, the effect of which cannot be predicted and may be adverse to us or our stockholders.

While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. We continue to work with our tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on us.

Trading on the OTC Markets may be volatile and sporadic, which could depress the market price of our common stock and make it difficult for our stockholders to resell their shares.

Our common stock has been quoted on the OTC Markets. Trading in stock quoted on the OTC Markets is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with our operations or business prospects. This volatility could depress the market price of our common stock for reasons unrelated to operating performance. Moreover, the OTC Markets is not a stock exchange, and trading of securities on the OTC Markets is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like the NYSE MKT. Accordingly, shareholders may have difficulty reselling any of their shares and the lack of liquidity may negatively impact our ability to pursue strategic alternatives.

Climate change initiatives could materially and adversely affect our business, financial condition, and results of operations.

Both domestic and international legislation to address climate change by reducing greenhouse gas emissions and establishing a price on carbon could create increases in energy costs and price volatility. Considerable international attention is now focused on development of an international policy framework to address climate change. Consumers and businesses also may change their behavior on their own as a result of these concerns. We will need to respond to new laws and regulations as well as consumer and business preferences resulting from climate change concerns. We may face cost increases, asset value reductions and operating process changes. The impact on our business will likely vary depending on specific attributes, including reliance on or role in carbon intensive activities.

Item 1b. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We do not own any property but utilize approximately 75 square feet of office space in London from Tiziana for which we reimburse Tiziana at cost through a shared services agreement. We believe that our existing facilities are adequate to meet our current needs for the foreseeable future, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms if needed.

Item 3. Legal Proceedings

We are not party to any material legal matters or claims. In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market information

Our common stock has traded on the OTC QB under the symbol "ACUT" since March 23, 2022.

Number of Stockholders

As of April _8_, 2022, we had approximately ___ stockholders of record of our common stock.

Dividend Policy

Historically, we have not paid any dividends to the holders of shares of our common stock and we do not expect to pay any such dividends in the foreseeable future as we expect to retain our future earnings for use in the operation and expansion of our business.

Transfer Agent

Our transfer agent for our common stock is Philadelphia Stock Transfer, Inc.

Item 6: [Reserved]

Not applicable.

Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

We operate a life sciences company focused on improving outcomes for patients with cancer. Our plan is to develop and commercialize a variety of products in the diagnostics, pharmaceutical and medical device spaces that enable more informed treatment planning and more effective treatment options for patients. Our initial approach will be the commercialization of a proprietary genomic platform, StemPrint, for recurrence risk stratification of different types of cancer. To augment this unique offering we also plan to provide ancillary commodity testing (e.g., hereditary genetic testing, somatic mutation testing) to provide additional information and value to our clients.

StemPrintER Sciences Limited "StemPrintER" was transferred to the Accustem Sciences Limited on October 30, 2020 pursuant to the demerger of the StemPrintER and SPARE projects from Tiziana. The objective of the demerger was to maximize value to the shareholders of Tiziana through the further commercialization of the StemPrintER project and its assets and intellectual property. The Demerger will allow us to continue its collaboration strategy to further develop, validate and commercialize the StemPrintER/SPARE platform as a separate listed company with related party receivable reserves of $1,353,373 (£1,000,000).

Since our inception, we have devoted substantially all of our resources to conducting research and development of our product candidate. Our revenue is expected to be derived from different sources including standard private third-party and government medical insurance coverage and reimbursement models. On completion of the demerger, Tiziana transferred $1,353,373 in cash to StemPrintER Sciences Limited and the entire issued share capital of StemPrintER to the Company and has agreed to invest a further $2,706,746 (£2,000,000) in our equity securities if and when we list on an Exchange.

We expect our expenses to increase substantially in connection with our ongoing development activities related to our preclinical and clinical programs. We intend to conduct further validation and utility studies with the intention of filing for regulatory review under the CLIA system and, ultimately, for reimbursement review. We also may pursue a strategy to achieve appropriate regulatory review with European and Asian regulatory agencies to
expand the addressable market for its products.

In addition, upon the effectiveness of this registration statement, we expect to incur additional costs associated with the expansion of our management team and operating as a public company in the United States. We expect that our expenses and capital requirements will increase substantially in the near to mid-term as we:

- build out corporate headquarters and a CLIA-certified laboratory in Phoenix, AZ;
- continue our research and development efforts;
- seek regulatory approvals for any product candidates that successfully complete clinical trials; and
- add clinical, scientific, operational financial and management information systems and personnel, including personnel to support our product development and potential future commercialization claims.

As a result, we may need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

Financial Operations Overview

We have no products approved for commercial sale and have not generated revenue to date. We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of $54,248 and $670,614 for the period from June 5, 2020 to December 31, 2020 and the year ended December 31, 2021, respectively. As of December 31, 2021, we had an accumulated deficit of $724,862. Substantially all of our net losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

Segment Information

As of December 31, 2021, we viewed our operations and managed our business as one operating segment consistent with how our chief operating decision maker, our Chief Executive Officer, makes decisions regarding resource allocation and assessing performance. As of December 31, 2021, substantially all of our assets were located in the United States. Our headquarters and operations are located in New York, NY and London, UK.

Research and development expense

Research and development costs are expensed as incurred. These costs consist of internal and external expenses, as well as depreciation expense on assets used within our research and development activities. Internal expenses include the cost of salaries, benefits, and other related costs, including stock-based compensation, for personnel serving in our research and development functions. External expenses include development, clinical trials, patent costs, and regulatory compliance costs incurred with research organizations, contract manufacturers, and other third-party vendors. License fees paid to acquire access to proprietary technology are expensed to research and development, unless it is determined that the technology is expected to have an alternative future use. All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred to research and development expense due to the uncertainty about the recovery of the expenditure. We record costs for certain development activities, such as preclinical studies and clinical trials, based on our evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense, as applicable. Our recording of costs for certain development activities requires us to use estimates. We believe our estimates and assumptions are reasonable under the current conditions; however, actual results may differ from these estimates.

Research and development expenses account for a significant portion of our operating expenses. We plan to incur research and development expenses for the foreseeable future as we expect to continue the development of our product candidates. We anticipate that our research and development expenses will be higher in fiscal year 2022 and subsequent periods as compared to the prior periods presented herein as we prepare to establish a CLIA lab.

Our research and development expenses are not currently tracked on a program-by-program basis for indirect and overhead costs. We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying, developing, and commercializing product candidates.

At this time, due to the inherently unpredictable nature of preclinical and clinical developments as well as regulatory approval (or authorization) and commercialization, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in our continued development and commercialization efforts. As a result of these uncertainties, successful development and completion of clinical trials as well as regulatory authorization or approval and commercialization are uncertain and may not result in authorized or approved and commercialized products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We will continue to make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to our ability to enter into collaborations with respect to each product candidate, the scientific and clinical success of each product candidate as well as ongoing assessments as to the commercial potential of each product candidate.

General and administrative expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits, insurance, and stock-based compensation expense, for employees in executive, accounting, commercialization, human resources, and other administrative functions. General and administrative expense also includes expenses related to pre-commercial activities, corporate facility costs, insurance premiums, legal fees related to corporate matters, and fees for auditing, accounting, and other consulting services.

We anticipate that our general and administrative expenses will increase in fiscal year 2022 as compared to the prior periods presented herein as a result of higher corporate infrastructure costs including, but not limited to accounting, legal, human resources, consulting, investor relations, and public company insurance fees.

Results of Operations

The following discussion and analysis of our results of operations includes a comparison of the year ended December 31, 2021 to the period from June 5, 2020 (date of inception) to December 31, 2020:

	Year Ended December 31, 2021	For the Period from June 5, 2020 (inception) to December 31, 2020	$ Change	% Change
Revenue	$ —	$ —	$ —	—%
Research and development expenses	73,335	5,748	67,587	1176%
General and administrative expenses	597,279	48,500	548,779	1132%
Loss from operations	670,614	54,248	616,366	1136%
Loss, before income tax	(670,614)	(54,248)	(616,366)	1136%
Income tax benefit (expense)	—	—	—	—%
Net loss	$ (670,614)	$ (54,248)	$ (616,366)	1136%

Research and development

Research and development expenses increased $67,587 in 2021 as compared to 2020. The increase primary related to a full year of patent related expenses.

General and administrative

General and administrative expenses increased $548,779 in 2021 as compared to 2020. The increase primarily related to a full year of operations and costs related to legal fees and other compliance expenses.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue and have incurred significant operating losses. Our potential products are at various phases of development. We do not expect to generate significant revenue from product sales for several years, if at all. Pursuant to the demerger, Tiziana committed to transfer $1,353,373 (£1,000,000) in cash to StemPrintER and the entire issued share capital of StemPrintER to the Company. The $1,353,373 in cash was paid in January 2022, and Tiziana agreed to invest $2,706,746 (£2,000,000) in cash for additional shares of the Company. Our cash flows may fluctuate and are difficult to forecast and will depend on many factors.

Cash Flows

The following table summarizes our cash flows:

	For the year ended December 31, 2021	For the period from June 5, 2020 (inception) to December 31, 2020
Cash flows from operating activities	$ —	$ —
Cash flows from investing activities	—	—
Cash flows from financing activities	—	—
Net increase in cash and cash equivalents	—	—
Cash and cash equivalents at beginning of period	—	—
Cash and cash equivalents at end of period	$ —	$ —

The Company did not generate any cash flows through December 31, 2021 as cash was funded by a related party.

Operating Activities

There were no cash flows from operating activities during the year ended December 31, 2021 and for the period from June 5, 2020 through December 31, 2020 since all cash activities were funded by a related party.

Investing Activities

There was no net cash used in or provided by investing activities for the year ended December 31, 2021 or the period June 5, 2020 (period of inception) through December 31, 2020.

Financing Activities

There was no net cash received in financing investing activities for the year ended December 31, 2021 or the period June 5, 2020 (period of inception) through December 31, 2020. There is a cash receivable balance due from related party of $1,558,251 for shares related to the demerger and supplemental dermerger agreements.

Market Capital Expenditure Commitments

We have no material commitment for capital expenditures.

Funding Requirements

We expect that our expenses will increase and operating losses will be generated, and we have $724,862 of accumulated deficit as at December 31, 2021. Based on our current plans, we believe our existing cash and cash equivalents will be not be sufficient to fund our operations and capital expenditure requirements into 2023. Through December 31, 2021, the Company has received financial support from a related party, which resulted in a net related party balance of $1,367,414, which $1,288,310 was settled for cash in January 2022. We expect to incur substantial additional expenditures in the near term to support our acceleration of activities. We expect to incur net losses for the foreseeable future. Our ability to fund our product development and clinical operations as well as commercialization of our product candidates, will depend on the amount and timing of cash received from planned financings. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our product candidates;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the emergence of competing technologies and products and other adverse marketing developments;
- the effect on our product development activities of actions taken by the FDA, EMA or other regulatory authorities;
- our degree of success in commercializing our product candidates, if and when approved; and
- the number and types of future products we develop and commercialize.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity financings, debt financings, collaborations with other companies or other strategic transactions. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with US GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in our consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Stock-Based Compensation

We account for share-based payment awards issued to employees and members of our Board by measuring the fair value of the award on the date of grant and recognizing this fair value as stock-based compensation using a straight-line basis over the requisite service period, generally the vesting period.

Related parties

Parties are related to the Company if the parties, directly or indirectly, through one or more intermediaries, control, are controlled by, or are under common control with the Company. Related parties also include principal owners of the Company, its management, members of the immediate families of principal owners of the Company and its management and other parties with which the Company may deal with if one party controls or can significantly influence the management or operating policies of the other to an extent that one of the transacting parties might be prevented from fully pursuing its own separate interests.

Off-Balance Sheet Arrangements

We have no other off-balance sheet arrangements that have had, or are reasonably likely to have, a material current or future effect on our consolidated financial statements or changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Recent Accounting Pronouncements

For information on recent accounting pronouncements, see our consolidated financial statements - Note 2 and the related notes found elsewhere in this annual report.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

As of December 31, 2021, we are not subject to any material market risk, including interest rate risk and foreign currency exchange rate risk. We additionally do not have material commodity price or equity price risks.

Foreign Currency Exchange Risk

There are two types of foreign currency exchange risks that the Company may be subject to: transaction and translation gains and losses. Foreign exchange transaction gains or losses are distinguished from translation gains or losses as follows: (i) translation adjustments do not involve the movement of cash, they are accounting conversion calculations of an existing functional currency to a reporting currency and (ii) transaction gains or losses which are based on an actual transaction that requires formal payment at a future point in time.

The Company maybe subject to foreign currency exchange risk relating to the translation of certain assets, liabilities, and income and expense accounts. The translation adjustment for assets and liabilities is reflected in the other accumulated comprehensive income (loss) caption included in the stockholders' equity section or our consolidated balance sheet. The Company uses the local currency as its functional currency. The assets and liabilities of the Company are translated into U.S. dollars at the rate of exchange at the end of the period. The income and expense accounts are translated using the average rate of exchange during the period. The Company typically incurs gains or loses of specified foreign currency translations, specifically related to related party receivables and payables, and these amounts are occasionally material. These gains and losses are reflected in the Company's consolidated statement of operations.

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

Item 8. Financial Statements and Supplementary Data

Index to the Consolidated Financial Statements

ACCUSTEM SCIENCES INC. AND SUBSIDIARY

December 31, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Shareholders of Accustem Sciences Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Accustem Sciences Inc. (the Company) as of December 31, 2021 and 2020, and the related statements of operations and comprehensive income (loss), shareholders' equity, and cash flows for the year ended December 31, 2021 and the period from June 5, 2020 (date of inception) to December 31, 2020, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the year ended December 31, 2021 and the period from June 5, 2020 (date of inception) to December 31, 2020 in the, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred operating losses since inception since inception. The Company also had an accumulated deficit of $724,862 at December 31, 2021. The Company is dependent on obtaining necessary funding from institutional investors or others, in order to continue their operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters also are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Mazars USA LLP

We have served as the Company's auditor since 2022.

New York, NY

April ___, 2022

ACCUSTEM SCIENCES INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	December 31, 2021	December 31, 2020
ASSETS		
Related party receivable	$ 1,353,373	$ 1,365,161
Total Current Assets	1,353,373	1,365,161
TOTAL ASSETS	$ 1,353,373	$ 1,365,161
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Account payable	$ 388,681	$ —
Related party payable	190,838	13,322
Accrued expenses	123,181	42,043
Total current liabilities	702,700	55,365
TOTAL LIABILITIES	702,700	55,365
Stockholders' Equity		
Preferred stock $.001 par value; 10,000,000 shares authorized; none issued and outstanding	—	—
Common stock $.001 par value; 150,000,000 shares authorized; 9,999,132 shares issued and outstanding	9,999	9,999
Additional paid-in capital	1,503,434	1,482,174
Related party subscription receivable	(204,879)	(206,663)
Accumulated other comprehensive income	66,981	78,534
Accumulated deficit	(724,862)	(54,248)
TOTAL STOCKHOLDERS' EQUITY	650,673	1,309,796
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,353,373	$ 1,365,161

ACCUSTEM SCIENCES INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

	Year Ended December 31, 2021	For the Period from June 5, 2020 (inception) to December 31, 2020
OPERATING EXPENSES		
Research and development expenses	$ 73,335	$ 5,748
General and administrative expenses	597,279	48,500
Total operating expenses	670,614	54,248
LOSS FROM OPERATIONS	(670,614)	(54,248)
LOSS, BEFORE INCOME TAX	(670,614)	(54,248)
Income tax benefit (expense)	—	—
NET LOSS	$ (670,614)	$ (54,248)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.07)	$ (0.01)
Weighted average common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	9,999,132	9,999,132
NET LOSS	$ (670,614)	$ (54,248)
Translation adjustments	(11,553)	78,534
COMPREHENSIVE (LOSS) INCOME	$ (682,167)	$ 24,286

ACCUSTEM SCIENCES INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Related Party Subscription Receivable	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
	Number of Shares	Amount					
Balance at June 5, 2020 (date of inception)	—	$ —	$ —	$ —	$ —	$ —	$ —
Issuance of common stock in relation of demerger agreement of StemprintER	9,520,069	9,520	1,286,463	—	—	—	1,295,983
Issuance of common stock in relation of associated supplemental demerger agreement of StemprintER	479,063	479	195,711	(196,190)	—	—	—
Foreign currency translation adjustment	—	—	—	(10,473)	78,534	—	68,061
Net loss	—	—	—	—	—	(54,248)	(54,248)
Balance at December 31, 2020	9,999,132	9,999	1,482,174	(206,663)	78,534	(54,248)	1,309,796
Stock based compensation	—	—	21,260		—	—	21,260
Foreign currency translation adjustment	—	—	—	1,784	(11,553)	—	(9,769)
Net loss	—	—	—		—	(670,614)	(670,614)
Balance at December 31, 2021	9,999,132	$ 9,999	$ 1,503,434	$ (204,879)	$ 66,981	$ (724,862)	$ 650,673

ACCUSTEM SCIENCES INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2021	For the Period from June 5, 2020 (date of formation) to December 31, 2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (670,614)	$ (54,248)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	21,260	—
Changes in assets and liabilities:		
Account payable	394,666	—
Related party payable	172,966	13,054
Accrued expenses	81,722	41,194
NET CASH FLOWS FROM OPERATING ACTIVITIES	—	—
NET CHANGE IN CASH	—	—
CASH, BEGINNING OF YEAR	—	—
CASH , END OF YEAR	$ —	$ —
Non cash items investing and financing activities:		
Shares issued for the demerger agreement of StemprintER/ Related party receivable	$ —	$ 1,295,983
Shares issued for the associated supplemental demerger agreement of StemprintER/ Related party subscription receivable	$ —	$ 196,190

1. DESCRIPTION OF BUSINESS

Accustem Sciences Inc. and its subsidiary ("the Company") was incorporated on July 28, 2021, in Delaware, United States. The Company is an early- stage life sciences company committed to developing and commercializing novel products for the treatment and management of many cancers. The principal activities of the Company are that of a genomics-based personalized medicine business, particularly focused on breast cancer patients.

The consolidated position of the Company is a result of the demerger of the legal entity StemPrintER Sciences Limited ("StemPrintER") from Tiziana Life Sciences plc ("Tiziana") by Accustem Sciences Limited ("Limited") on October 30, 2020. Limited was incorporated on June 5, 2020. On March 12, 2021 and further amended on May 7, 2021 and June 1, 2021, Limited filed a registration statement on Form 20-F with the US Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934, to effect the demerger transaction. The registration statement was declared effective on July 1, 2021. The transaction is as detailed in the steps below:

In September 2020, Tiziana transferred all the ownership rights and intellectual property relating to StemPrintER along with a commitment to pay $1,353,373 in cash to its wholly owned subsidiary, StemPrintER in exchange for 3,070,000 shares of the subsidiary.

On October 5, 2020, Limited entered into an agreement with Tiziana to acquire the outstanding shares of StemPrintER, including the ownership rights and intellectual property relating to the StemPrintER project, the SPARE project and cash receivable of $1,353,373. In exchange for the transfer of ownership, the Limited issued a total of 9,520,069 ordinary shares of $0.001 par value to Tiziana shareholders on a one for one basis based on the Tiziana ownership as at October 30, 2020. On October 30, 2020, a supplemental demerger agreement of StemprintER was executed and 479,063 of ordinary shares of $0.001 par value were issued for consideration (see Related Party Note 7) of $204,879 in relation to the associated option and warrant holders of Tiziana. The share composition noted are post share consolidation as further described below.

On November 1, 2021, Limited announced its intention to put in place a new parent company (formerly Accustem Sciences Limited and subsidiary), being Accustem Sciences, Inc., a Delaware-incorporated company, pursuant to a Scheme of Arrangement under United Kingdom "UK" law. Pursuant to Rule 12g-3(a) of the Securities Act of 1934, on December 1, 2021 ("Effective Date"), Limited completed the company's redomiciliation from the UK to Delaware, United States. In connection with the completion of the redomiciliation, the Company acquired all of the issued share capital of Limited in exchange for the issuance of the Company's common stock and became the successor issuer to Limited. The Company and its subsidiary will conduct the same business and operations after the redomiciliation as Limited had been conducting prior to the redomiciliation and there are no expected changes to the day-to-day operation of the business of the Company or its strategy. Due to the entities being under common control, the acquisition was accounted for based on existing carrying amounts. The consolidated financial statements for periods prior to the redomiciliation are the consolidated statements of Limited as the predecessor to the Company for accounting and reporting purposes. On December 30, 2021, the Company and the Board approved for the dissolution of Limited, effective December 30, 2021. Limited's wholly owned subsidiary, StemPrintER Sciences Limited, common shares was transferred to Accustem Sciences, Inc. This dissolution had no impact on the Company's results for the year ended December 31, 2021.

On the effective date of the redomiciliation, the Company also completed a 20:1 share consolidation and the number of outstanding common shares was reduced from 199,988,724 to 9,999,132 of common stock (subject to adjustment as applicable due to the rounding of fractional shares. Therefore, (i) every 20 ordinary shares, £0.01 par value per share, of Limited (the "Limited Ordinary Shares") were exchanged for one share of common stock, $0.001 par value per share, of the Company (the "Company Common Stock") and (ii) every 10 Accustem American Depository Shares ("ADS") representing two Limited Ordinary Shares were exchanged for one share of the Company's Common Stock, which resulted in the Company becoming the holding company of Limited. Also, every 20 options held by a Limited holder converted and received one option to purchase a common share of the Company as further described in Note 6.

All share and per share amounts in these consolidated financial statements and related notes for periods prior to the redomiciliation have been retroactively adjusted to reflect the effect of the 20:1 exchange ratio.
These consolidated financial statements have been prepared for the periods from June 5, 2020 (period of inception) to December 31, 2020 and for the year ended December 31, 2021.

Shares of Limited's common stock issued in connection trade over-the-counter market under the ticker symbol "ACMSY". On March 23, 2022 the Company's common stock shares began trading within the OTC Markets under the ticker symbol "ACUT".

Impact of the COVID-19 Pandemic

In early 2020, an outbreak of the novel strain of coronavirus (COVID-19) emerged globally. As a result, there have been mandates from federal, state and local authorities resulting in an overall decline in economic activity. There have been no material impacts from COVID-19 on the Company's operations for the periods ended December 31, 2021 and 2020. However, it is possible that the pandemic will continue to significantly impact economies worldwide, which could result in adverse effects on the Company's operations. The extent of the impact of COVID-19 on operations, liquidity, financial condition, and results of operations remain uncertain at this time.

Liquidity and Going Concern

The consolidated financial statements have been prepared on the going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business.

The Company has financed its activities principally from support from a related party. The Company has incurred a net loss in every fiscal period since inception. For the year ended December 31, 2021, the Company incurred a net loss of $670,614. The Company has an accumulated deficit as of December 31, 2021 of $724,862. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, further development of its technology and products, and expenses related to the commercialization of its products.

Management believes that the Company does not have sufficient cash and current assets to support its operations through at least 12 months from the issuance date of these consolidated financial statements, and will require significant additional cash resources to continue its planned research and development activities.

The Company will need additional funds for promoting new products and working capital required to support research and development activities and generate sales from its products. There can be no assurance, however, that such financing will be available when needed, if at all, or on favorable terms and conditions. The precise amount and timing of the funding needs cannot be determined accurately at this time, and will depend on a number of factors, including the quality of product development efforts, management of working capital, and the continuation of normal payment terms and conditions for purchase of services.

Subsequent to year end, management notes the Company has received net repayment of related party receivable/payable in the amount of $1,288,310 from Tiziana, see Note 7 - Related Party Transactions. Additionally, the Company has received an additional capital contribution through the issuance of ordinary shares from Tiziana in the amount of $2,675,940, see Note 10 - Subsequent Events.

In order to address its capital needs, including its planned research and development activities and other expenditures, the Company is actively pursuing additional equity financing in the form of a private placement. The Company has been in ongoing discussions with institutional investors and other parties with respect to such possible offerings. Adequate financing opportunities might not be available to the Company, when and if needed, on acceptable terms or at all. If the Company is unable to obtain additional financing in sufficient amounts or on acceptable terms or if the Company fails to consummate the private placement or a public offering, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs and product portfolio expansion, which could adversely affect its operating results or business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding in terms acceptable to the Company to fund continuing operations, if at all. After considering the uncertainties, management determined it is appropriate to continue to adopt the going concern basis in preparing the consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below.

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in United States of America ("GAAP") and are in U.S. dollars. Unless otherwise indicated, all references to "$" are to United States dollars, and all references to "GBP" are to Great Britain Pounds. The Company's reporting currency is U.S. dollars.

Basis of Consolidation

The accompanying audited consolidated financial statements include the accounts of Accustem Sciences Inc. as well as its wholly-owned subsidiary. The Company consolidates all entities over which the Company has the power to govern the financial and operating policies and therefore exercises control, and upon which the Company has a controlling financial interest. The existence and effect of both current voting rights and potential voting rights that are currently exercisable or convertible are considered when assessing whether control of an entity is exercised. The subsidiary is consolidated from the date at which the Company obtains control and are de-consolidated from the date at which control ceases.

Inter-company transactions and balances between companies are eliminated upon consolidation. Accounting policies of the subsidiary has been changed where necessary to ensure consistency with the policies adopted by the Company.

Prior to the redomiciliation, Limited reported its consolidated financial statements in accordance with International Financial Reporting Standards ("IFRS"). Following the redomiciliation, the Company transitioned to GAAP and applied GAAP retrospectively for all prior periods presented. In the opinion of management, all necessary adjustments (consisting of normal recurring adjustments, intercompany adjustments, reclassifications and non-recurring adjustments) have been recorded to present fairly our financial position as of December 31, 2021 and 2020, and the results of operations, and cash flows for the periods ended December 31, 2021 and 2020. The Company and its subsidiary have historically been under common control. The redomiciliation and related internal reorganization was accounted for consistent with a reorganization of entities under common control in accordance with ASC 805 - *Business Combinations*. Accordingly, the transfer of the assets and liabilities and exchange of shares was recorded in the new entity at their carrying amounts from the transferring entity at the date of transfer. The financial information for all periods in the financial statements presented prior to the reorganization are presented on a consolidated basis for all periods upon which the entities are under common control.

Comprehensive income(loss)

Comprehensive income (loss) of all periods presented is comprised primarily of net loss and foreign currency translation adjustments.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management of the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

Risk and Uncertainties

The Company is subject to a number of risks similar to those of other companies of similar size in its industry, including but not limited to, the success of its exploration to research and development activities, need for additional capital (or financing) to fund operating losses, competition from substitute products and services from larger companies, protection of proprietary technology, patent litigation, dependence on key individuals, and risks associated with changes in information technology.

Impairment of Long-lived Assets

The Company reviews the recoverability of its long-lived assets (or asset groups) in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 360 ("ASC 360") *Property, Plant, and Equipment*, whenever events or changes in circumstances indicate that the carrying amount of the long-lived asset (group) might not be recoverable. The assessment for potential impairment is based primarily on the Company's ability to recover the carrying value of its long-lived assets from expected future undiscounted cash flows. If the total expected future undiscounted cash flows are less than the carrying amount of the assets, a loss is recognized for the difference between fair value (computed based upon the expected future discounted cash flows) and the carrying value of the assets.

Income Taxes

The Company accounts for income taxes under ASC 740 - *Income Taxes*. For federal and state income taxes, deferred tax assets and liabilities are recognized based upon the differences between the financial statement and the tax basis of assets and liabilities. In addition, deferred tax assets are also recorded with respect to net operating losses and other tax attribute carryforwards. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded when it is not more likely than not that the tax benefit from the deferred tax assets will be realized.

The Company intends to continue maintaining a full valuation allowance on its deferred tax assets until there is sufficient evidence to support reversal of all or a portion of the allowances. In establishing the full valuation allowance position, the Company considered all available evidence, including all potential sources of taxable income, future reversals of taxable temporary differences, projections of taxable income, and income from tax planning strategies, as well as any other available and relevant information. Existing valuation allowances are re-examined each period. If it were determined that it is more likely than not that a deferred tax asset will be realized, the appropriate amount of the valuation allowance, if any, would be released in the period this determination is made.

Tax positions not deemed to meet a more-likely-than-not threshold would be recorded as a tax expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of December 31, 2021 and 2020. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority.

Research and Development Expenses

Research and product development costs are expensed as incurred under ASC 730 - *.Research and Development*. Research and development expenses primarily consist of costs associated with the preclinical and clinical development of the Company's product candidate portfolio, including but not limited to payments to Clinical Research Organizations ("CROs"), the manufacturing of clinical trial material, preclinical research activities, consultants and personnel needed to perform research and development activities, intellectual property, as well as costs to license intellectual property that is an in-process research and development asset with no alternative future use.

Segment Information

The Company applies ASC 280, *Segment Reporting*, in determining reportable segments for its financial statement disclosure. Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer ("CEO"). The Company has determined that it operates as a single operating segment and has one reportable segment.

Fair Value of Financial Instruments

The Company classifies a financial instrument, or its component parts, as a financial liability, a financial asset or an equity instrument in accordance with the substance of the contractual arrangement and the definitions of a financial liability, a financial asset and an equity instrument.

The Company evaluates the terms of the financial instrument to determine whether it contains an asset, a liability or an equity component. Such components shall be classified separately as financial assets, financial liabilities or equity instruments.

The Company's financial liabilities include trade and other payables. The carrying value of such amounts approximate fair value based on the short-term nature of the items. The Company does not hold any financial assets or liabilities at fair value through profit or loss or fair value through other comprehensive income

Stock-based compensation expenses

The Company recognizes stock-based compensation expense for awards of equity instruments to employees and non-employees based on the grant-date fair value of those awards in accordance with ASC 718 - *Stock Compensation.* The grant-date fair value of the award is recognized as compensation expense ratably over the requisite service period, which generally equals the vesting period of the award. The Company accounts for actual forfeitures in the period the forfeiture occurs.

The Company's stock-based payments include stock options. Stock-based compensation expense is included in general and administrative expenses and research and development expenses in the Statements of Operations.

Loss per Share

The Company computes loss per share in accordance with ASC 260 - *Earnings per Share*. Basic net loss per common share is computed by dividing net loss by the weighted average number of shares of common shares outstanding during the period. Diluted net loss per share of common stock is computed by giving effect to all potential dilutive shares of common stock, including options, restricted stock units ("RSUs") and performance awards. Basic and diluted net loss per share of common stock were the same for all periods presented as the impact of all potentially dilutive securities outstanding was anti-dilutive.

Foreign Currencies

The consolidated financial statements are presented in United States dollars which is the Company's reporting and functional currency as the Company's operating and capital costs are transacted in U.S. dollars. The Company's fully consolidated subsidiary functional currency continued to be GBP, which is the currency of the primary economic environment in which the entities operated.

The financial results and position of foreign operations whose functional currency was different from the Company's reporting currency were translated as follows:

- assets and liabilities were translated at year-end exchange rates prevailing at that reporting date;
- income and expenses were translated at average exchange rates for the period; and
- equity transactions including retained earnings/accumulated deficit were translated at the exchange rates prevailing at the date of the transaction.

Gains and losses arising from translations or settlements of foreign currency denominated transactions or balances were included in the determination of income. "Other comprehensive loss," in the consolidated statements of comprehensive loss, included foreign currency translation adjustments for the periods ended December 31, 2021 and 2020.

Recently Issued and Adopted Accounting Standards

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, the consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

The JOBS Act does not preclude an emerging growth company from early adopting new or revised accounting standards. As described below, the Company has early adopted certain accounting pronouncements before the due date for emerging growth companies. The Company expects to use the extended transition period for any other new or revised accounting standards during the period for which the Company remains an emerging growth company.

The Company considers the applicability and impact of all Accounting Standards Updates ("ASUs"). ASUs not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the Company's financial statements.

Effective June 5, 2020, ASU 2018-07, "*Compensation—Stock Compensation* - ASC 718." This update is intended to reduce cost and complexity and to improve financial reporting for stock-based payments issued to non-employees, such as service providers, consultants, external legal counsel, and suppliers. The ASU expands the scope of Topic 718, *Compensation—Stock Compensation*, which currently only includes stock-based payments issued to employees, to also include stock-based payments issued to non-employees for goods and services. Consequently, the accounting for stock-based payments to non-employees and employees will be substantially aligned. This standard will be effective for financial statements issued by public companies for the annual and interim periods beginning after December 15, 2018. Early adoption of the standard is permitted. The standard will be applied in a retrospective approach for each period presented. We did not record an adjustment as of June 5, 2020, as our adoption of ASU 2018-07 did not have a material impact on the Company's consolidated financial statements.

Effective July 1, 2020, we early adopted ASU 2019-12, "Income Taxes -ASC 740 : *Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in ASC 740. The amendments also improve consistent application of and simplify GAAP for other areas of ASC 740 by clarifying and amending existing guidance. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The adoption of ASU 2019-12 did not have a material impact on the Company's consolidated financial statements.

Issued Accounting Standards Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02 as amended, *Leases* ASC 842 which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company has evaluated Topic 842 and believes that there will be an immaterial on the Company's financial statements and related disclosures with the adoption of the standard as of January 1, 2022. The Company has no outstanding leases.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging— Contracts in Entity's Own Equity* (Subtopic 815-40) (ASU 2020-06), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. ASU 2020-06 removes from U.S. GAAP the separation models for (1) convertible debt with a cash conversion feature ("CCF") and (2) convertible instruments with a beneficial conversion feature ("BCF"). As a result, after adopting the ASU's guidance, entities will not separately present in equity an embedded conversion feature in such debt. Instead, they will account for a convertible debt instrument wholly as debt, and for convertible preferred stock wholly as preferred stock (i.e., as a single unit of account), unless (1) a convertible instrument contains features that require bifurcation as a derivative under ASC 815 or (2) a convertible debt instrument was issued at a substantial premium. ASU 2020-06 is effective for public business entities that meet the definition of an SEC filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The Company will adopt the provisions of ASU 2020-06 effective January 1, 2024 and is currently assessing potential impacts.

In May 2021, the FASB issued ASU 2021-04, "*Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity Classified Written Call Options*" ("ASU 2021-04"), which introduces a new way for companies to account for warrants either as stock compensation or derivatives. Under the new guidance, if the modification does not change the instrument's classification as equity, the company accounts for the modification as an exchange of the original instrument for a new instrument. In general, if the fair value of the "new" instrument is greater than the fair value of the "original" instrument, the excess is recognized based on the substance of the transaction, as if the issuer has paid cash. The effective date of the standard is for interim and annual reporting periods beginning after December 15, 2021 for all entities, and early adoption is permitted. The Company is currently evaluating the impact of the new guidance and does not expect the adoption of this guidance will have a material impact on its consolidated financial statements and disclosures.

3. ACQUISITION OF STEMPRINTER SCIENCES LIMITED

The consolidated position of the Company is a result of the demerger of StemPrintER from Tiziana on October 30, 2020. The transaction is detailed in the steps below and described in Note 1.

On October 5, 2020, Limited entered into an agreement with Tiziana to acquire its subsidiary StemPrintER, including the ownership rights and intellectual property relating to the StemPrintER project, the SPARE project and cash receivable of $1,353,373. In exchange for the transfer of ownership, Limited issued a total of 9,520,069 ordinary shares of $0.001 par value to Tiziana shareholders on a one for one basis based on the Tiziana ownership as at October 30, 2020. In addition, on October 30, 2021, a supplemental demerger agreement was executed and there were 479,063 of ordinary shares of $0.001 par value issued for consideration of $204,879 in relation to the associated option and warrant holders of Tiziana. The Company considered ASC 805 - *Business Combinations* and ASC 730 - *Research and Development* in determining how to account for the transaction. As the transaction was between entities that were ultimately controlled by the same parties, the acquisition has been treated as a common control combination under ASC 805-50 - *Business Combinations*, therefore the carrying value of contributed assets remained unchanged and were recorded at historical costs. The share composition noted above are post share consolidation as noted in Note 1.

The transfer of all the ownership rights and intellectual property was treated as an asset transfer. The treatment as a separate asset acquisition at this stage reflected the fact that, immediately prior to transfer, Tiziana carried out only limited maintenance type activity on the StemPrintER project and the concentration of fair value was in the StemPrintER intellectual property asset.

In addition, per the terms of the supplemental agreement to the demerger agreement, Tiziana agreed to invest for $2,706,746 (£2,000,000 GBP) in exchange for additional shares of the Company. See Note 10 - Subsequent Events for further details.

4. LICENSE

On June 24, 2014, Tiziana entered into an exclusive license agreement with IEO/University of Milan, pursuant to which it obtained a worldwide, royalty-bearing, exclusive license under certain patents and a worldwide, royalty-bearing, non-exclusive license under certain know-how, respectively, of IEO/University of Milan to develop and commercialize licensed products in connection with a multi-gene prognostic tool. This license was assigned to the Company pursuant to the terms of the acquisition of StemprintER as noted in Note 3.

The license provides for full control and authority over the research, development and commercialization of licensed products and are required to use commercially reasonable efforts in connection with the development and commercialization of the licensed products. Following completion of the research plan, the following various diligence requirements must be met:

For the term of the license, the following milestone payments were required to be made (converted from EUROS to USD using exchange rate of €1:$1.1324)

- €50,000 ($56,620) within 30 days of completion of development of a commercial test;
- €100,000 ($113,240) within 30 days of the first commercial sale of a licensed product; and
- €150,000 ($169,860) within 30 days of first regulatory approval in the U.S. or any other major market.

Tiziana was also required, as licensee prior to the assignment to us of the License, to fund €50,000 ($56,620) per year for sponsored research for up to four years from the effective date of the license (2014-2018), subject to certain conditions. The license also requires payment for all ongoing patent prosecution and maintenance costs and for the royalty term (until the expiration of the last claim in an issued, unexpired patent within the licensed patents or a claim that has not been pending more than four years which covers the sale of such licensed product or service in such country) a royalty of 1.5% on net sales of licensed products and services (and a 15% royalty of sub-license revenues for each country for the term of the license). The license agreement may be terminated at any time on 30 days' notice and either party may terminate the license by written notice for a material payment breach or any other material breach, subject to 45-day and 120-day periods, respectively. Absent early termination, the license will remain in effect, on a product by product and country by country basis, until the date on which the patents and patent applications expire. The license may also be terminated in the case of insolvency.

For the period ended December 31, 2021 and year ended December 31, 2021, the Company recognized $0 and $0 in expenses related to this license agreement.

5. LOSS PER SHARE

Basic and diluted net loss per common share were the same since the inclusion of common shares issuable pursuant to the exercise of options in the calculation of diluted net loss per common shares would have been antidilutive.

For the periods ended December 31, 2021 and 2020, loss per share of the Company are as follows:

	For the Year Ended December 31, 2021	For the Period from June 5, 2020 (date of inception) to December 31, 2020
Numerator:		
Net Loss	$ (670,614)	$ (54,248)
Net loss attributable to common shareholders	$ (670,614)	$ (54,248)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	9,999,132	9,999,132
Net loss per common share, basic and diluted	$ (0.07)	$ (0.01)

The Company's potentially dilutive securities, which include stock options, have been excluded from the computation of diluted net loss per common share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders is the same.

The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2021 and 2020 because including them would have had an anti-dilutive effect:

	For the Year Ended December 31, 2021	For the Period from June 5, 2020 (date of inception) to December 31, 2020
Stock options to purchase common stock outstanding	100,005	—
Total	100,005	—

6. STOCK BASED COMPENSATION

In August 2021, Limited adopted the 2021 Omnibus Equity Incentive Plan (the "Incentive Plan") The Incentive Plan provides that the Company may grant Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, and Other Stock-Based Awards to selected employees, directors, and independent contractors of the Company.

Each Option shall be exercisable at such time or times and subject to such terms and conditions set forth in the Incentive Plan, as shall be determined by the administrator in the applicable award agreement. Total shares authorized by the plan was 2,500,000. Options under the Incentive Plan are exercisable for up to 10 years from the date of issuance. There are 2,399,995 remaining available shares to be issued under the Incentive Plan at December 31, 2021. The number of shares of Common Stock that are reserved and available for issuance under the Incentive Plan shall be subject to an annual increase on the first day of each calendar year beginning with the first January 1 following the effective date and ending with the last January 1 during the initial ten-year term of the Plan as defined in Section 4(a) of the Incentive Plan.

On December 1, 2021 (the "Effective Date"), Limited completed the Company's redomiciliation from the United Kingdom to Delaware (see Note 1). As of the Effective Date, the option instruments to purchase Limited Ordinary Shares granted by Limited (the "Old Options") were exchanged automatically in consideration of the grant of new options by New Accustem which, in the opinion of the board of directors of Limited, are equivalent to the Old Options, but relate to the New Accustem Common Stock. As of the Effective Date, New Accustem assumed Limited's obligations under its 2021 Incentive Plan and other arrangements under which incentives in relation to Limited Ordinary Shares were agreed with before the effective date of the redomiciliation and the Company replaced all equity awards granted under the Limited Plan with equivalent equity awards for New Accustem Common Stock. Also, as of the Effective Date, New Accustem's 2021 Equity Incentive Plan (the "2021 Plan"), became effective. Any employee, director or consultant of New Accustem or any of its subsidiary is eligible to participate in the 2021 Plan.

For the year ended December 31, 2021, stock option activity of the Company are as follows:

	Number of share options	Weighted average exercise price	Weighted average remaining contractual life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2021	—	$ —	—	$ —
Issued	100,005	0.42	10 years	
Exercised	—	—	—	
Expired/Forfeited	—	—	—	
Outstanding at December 31, 2021	100,005	0.42	9.72 years	—
Vested and exercisable December 31, 2021	100,005	$ 0.42	9.72 years	$ —

The aggregate intrinsic value is calculated as the difference between the estimated fair value of the underlying common stock as of December 31, 2021 and the option exercise price.

All share options as of December 31, 2021 were fully vested at issuance date on August 1, 2021.

Total stock-based compensation expense recognized for both employees and non-employees was as follows for the year ended December 31, 2021:

	For the Year Ended December 31, 2021
Research and development	$ —
General and administrative	21,260
Total stock-based compensation expense	$ 21,260

The weighted average grant date fair value for stock options granted during the years ended December 31, 2021 was $0.16, respectively. The Company uses the Black- Scholes option pricing model to estimate the fair value of the option awards with the following weighted-average assumptions for the years ended December 31, 2021:

	For the Year Ended December 31, 2021
Risk-free interest rate	0.31%
Expected dividend yield	—%
Expected term	5 years
Expected volatility	59.00%

The risk-free interest rate assumption is determined using the yield currently available on U.K. Treasury zero- coupon issues with a remaining term commensurate with the expected term of the award. The Company has historically been a private company and lacks company-specific historical and implied volatility information. Management has estimated expected volatility based on similar public companies. Expected life of the option represents the period of time options are expected to be outstanding. The estimate for dividend yield is 0%, because the Company has not historically paid, and does not intend to pay, a dividend on common stock in the foreseeable future.

At December 31, 2021, there was no unrecognized compensation expense related to options.

7. RELATED PARTY TRANSACTIONS

Tiziana is a related party as it is under common control. The Company and Tiziana share directors, officers and significant shareholders. The Company has also been formed due to an acquisition of a subsidiary company from Tiziana, see Notes 1 and 3 for further details.

As of December 31, 2021 and 2020, $1,558,252 and $1,571,824 (which consists of the related party receivable and related party subscription receivable on the consolidated balance sheet), respectively, was due from Tiziana in relation to the demerger and supplemental demerger of Limited and StemPrintER as further discussed in Notes 1 and 3. This related party receivable was collected in January 2022, net of related party payables to Tiziana as discussed below.

Effective with the demerger agreement, the Company entered into a shared services agreement, where the Company outsources certain limited management and administrative services. The Company notes that the fees consist of payroll costs associated with time spent providing services for the Company and are based on actual time spent and the allocated payroll costs. In addition, the Company is charged, at cost, for utilization of certain office space. There was no mark-up associated with fees charged for these services. For the year ended December 31, 2021 and for the period of inception June 5, 2020 through December 31, 2020, the Company has incurred approximately $12,434 and $0, respectively.

At December 31, 2021 and December 31, 2020, $190,838 and $13,323 was also due to Tiziana, as Tiziana had paid for expenses on behalf of the Company.

8. INCOME TAXES

The domestic and foreign components of loss before income taxes are as follows:

	For the Year Ended December 31,	For the Period from June 5, 2020 (date of inception) to December 31,
Domestic	$ 341,904	$ —
Foreign	328,710	54,248
	$ 670,614	$ 54,248

A reconciliation of the provision for income taxes to the amount computed by applying the statutory income tax rate of 21% to the net loss before income taxes for the year ended December 31, 2021 and the date of inception (June 5, 2020) through December 31, 2020 are as follows:

	For the Year Ended December 31, 2021	For the Period from June 5, 2020 (date of inception) to December 31, 2020
Federal income taxes at statutory rates	21.0%	21.0%
State and local taxes, net of federal benefit	0.3%	—%
United Kingdom income rate differential	2.0%	4.0%
Change in valuation allowance	(23.3)%	(25.0)%
	—%	—%

For the year ended December 31, 2021 and the June 5, 2020 (date of inception) through December 31, 2020, the Company did not have any current tax and did not record a deferred income tax expense or benefit due to losses and a full valuation allowance.

Deferred income taxes reflect the net tax effects of differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The following table presents significant components of the Company's net deferred tax assets as of December 31, 2021 and 2020.

	December 31, 2021	December 31, 2020
Net operating loss carryforwards	$ 169,721	$ 13,562
Total deferred tax assets	169,721	13,562
Less: valuation allowance	(169,721)	(13,562)
Net deferred tax asset	$ —	$ —

As of December 31, 2021, the Company has available net operating loss carryforwards of $341,904 for federal income tax reporting purposes, $56,378 for state income tax reporting purposes, and $382,958 for United Kingdom income tax reporting purposes. The federal and the United Kingdom net operating loss carryforward will be carried forward indefinitely, and the state net operating loss carryforward will expire beginning in 2041.

In accordance with Section 382 of the Internal Revenue code, the usage of the Company's net operating loss carryforwards may be limited in the event of a change in ownership. A full Section 382 analysis has not been prepared and NOLs could be subject to limitation under Section 382.

The Company is subject to income taxes in the U.S., federal and state, and the United Kingdom. Tax regulations within each jurisdiction are subject to the interpretation of related tax laws and regulations and require significant judgment to apply. The Company's tax years remain open for examination by all tax authorities since inception.

9. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

The Company is involved from time to time in various claims, proceedings, and litigation. The Company establishes reserves for specific legal proceedings when it determines that the likelihood of an unfavorable outcome is probable, and the amount of loss can be reasonably estimated. Management has not identified any legal matters where it believes an unfavorable outcome is reasonably possible and/or for which an estimate of possible losses can be made.

10. SUBSEQUENT EVENTS

Issuance of New Option Awards

In January 2022, the Company granted to its employees, consultants, executive board 1,307,239 options under the Incentive Plan, to purchase the number of shares of the Company's stock. The exercise price of each option ranged from $1.06 to $2.13. The options were either fully vested at date of grant or included various vesting periods up to four years or completion of defined performance goals.

Issuance of Warrants

In January 2022, the Company granted 390,000 warrants.

Investment in the Company by Tiziana

On March 31, 2022, the Company issued 1,337,970 shares in the Company's stock to Tiziana Life Sciences Ltd, pursuant to a commitment made in October 2020 to purchase $2,675,940 (£2,000,000) shares in Accustem when the company listed its common stock.

Appointment of Executive Leadership Team

On March 3, 2022, the Company announced the appointment of a CEO, Wendy Blosser. Also joining the leadership team are Jeff Fensterer, as Chief Operations Officer, and Joe Flanagan, as Chief Business Officer.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Management's Annual Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal controls over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The Company's internal control over financial reporting are a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles ("US GAAP").

Because of their inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of management, the Company's Chief Executive Officer and the Company's Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial over financial reporting based on the framework described in Internal Control-Integrated Framework issued by the Commission of Sponsoring Organizations of the Treadway Commission, as revised in 2013. Based on that evaluation, management has concluded that the Company did not maintain effective internal control over financial reporting as of the period ended December 31 2021 due to the existence of the material weaknesses in internal control over financial reporting described below.

Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Management has determined that the Company did not maintain effective internal control over financial reporting as of the period ended December 31, 2021 due to the existence of the following material weaknesses identified by management:

Lack of Accounting Resources

The Company had a lack of accounting resources resulting in inadequate monitoring controls and other oversight procedures. Our management has determined that our disclosure controls and procedures and internal controls were ineffective due to weaknesses in our financial closing process, inadequate segregation of duties over authorization, review and recording of transactions, lack of accounting resources, as well as the financial reporting of such transactions.

Remediation efforts to address the material weakness relating to the Control Environment

Management intends to remediate this item in the following manner:

i. Recruit appropriately skilled accounting resources

Accordingly, management has determined that these control deficiencies constitutes a material weakness. Management will begin implementing the Remediation Plan described herein and intends to continue working on it through the year ended December 31, 2022.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal year that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None

Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth the names and ages of all of our current directors and executive officers. Our officers are appointed by, and serve at the pleasure of, the Company's Board of Directors (referred to herein as the "Board") and/or our Chief Executive Officer.

Name	Age	Position
Wendy Blosser	55	Chief Executive Officer
Jeff Fensterer	43	Chief Operating Officer
Joe Flanagan	47	Chief Business Officer
Keeren Shah	46	Chief Financial Officer
Gabriele Cerrone	50	Director
Dr. Kunwar Shailubhai, Ph.D., M.B.A.	68	Director
Willy Simon	70	Director
John Brancaccio	74	Director

Wendy Blosser

Wendy brings 25 years of success launching, relaunching and building organizations in diagnostic, surgical and capital sales, with a focus in Oncology and Women's Health. She has achieved record revenue growth at a variety of organizations from early-stage start ups to Fortune 500 companies. Most recently, Wendy has served as CCO at Agendia, Animated Dynamics and Biodesix. Prior to Biodesix, Wendy served as VP of Sales with Integrated Oncology (LabCorp subsidiary) where she lead the successful integration of Genzyme Genetics following its acquisiton for $925M. Before joining Integrated Oncology, she held several leadership roles with Cytyc Corporation prior to its $6.2B acquisition by Hologic.

Jeff Fensterer

Jeff has spent the last 20 years with start ups at various organizational stages, leading marketing and product strategy in his most recent roles at Agendia, Animated Dynamics and Biodesix. His scientific expertise and keen commercial perspective enable organizations to take clinical data and translate it into impactful product messaging and publication strategies. His exceptional track record in long-term strategic planning is enhanced by experience in a broad spectrum of roles including marketing, sales, R&D, market access, lab operations, clinical development, business development and IT. Jeff holds a MBA from Carnegie Mellon University.

Joe Flanagan

Joe has 25 years of sales excellence experience and is one of the most sought after talents in Oncology. He is a strategic expert, playing a leading role in the commercial development and successful launch of several product offerings from early-stage diagnostic start ups to large pharmaceutical companies. Prior to joining Accustem, Joe served as the VP of Sales for Precision Therapeutics as well as the VP of Market Development for Biodesix and Agendia. During his tenure, record revenues were realized as a result of his efforts to enhance the clinical agility and logistical focus of each company's sales team. Most recently, he led strategic development efforts with Ambry Genetics' Oncology franchise.

Keeren Shah

Keeren Shah serves as our Chief Financial Officer. Ms. Shah currently also serves as the Chief Financial Officer of OKYO Pharma Ltd and Rasna Therapeutics Inc. and Finance Director of Tiziana Life Sciences Ltd, having previously served as the Group Financial Controller for all businesses from June 2016 to July 2020. Prior to joining the Company, Ms. Shah spent 10 years at Visa, Inc. as a Senior Leader in its finance team where she was responsible for key financial controller activities, financial planning and analysis, and core processes as well as leading and participating in key transformation programmes and Visa Inc.'s initial public offering. Before joining Visa, Ms. Shah also held a variety of finance positions at other leading companies including Arthur Andersen and BBC Worldwide. She holds a Bachelor of arts with honours in Economics and is a member of the Chartered Institute of Management Accountants.

Gabriele Cerrone

Mr. Gabriele Marco Antonio Cerrone has founded ten biotechnology companies in oncology, infectious diseases and molecular diagnostics, and has listed seven of these companies on Nasdaq two to the Main Market and AIM Market in London. Mr. Cerrone co-founded Cardiff Oncology, Inc., an oncology company and served as its Co-Chairman; hewas a co-founder and served as Chairman of both Synergy Pharmaceuticals, Inc. and Callisto Pharmaceuticals, Inc. and was a Director of and led the restructuring of Siga Technologies, Inc. Mr. Cerrone also co-founded FermaVir Pharmaceuticals, Inc. and served as Chairman of the Board until its merger in September 2007 with Inhibitex, Inc. Mr. Cerrone served as a director of Inhibitex, Inc. until its US$2.5bn sale to Bristol Myers Squibb Co in 2012. Mr.Cerrone is the Executive Chairman and Founder of dual-listed Tiziana Life Sciences plc, an oncology focused therapeutics company; Co-Founder of Rasna Therapeutics Inc., a company focused on the development of therapeutics for leukaemias; Co-Founder of Hepion Pharmaceuticals, Inc.; Executive Chairman and Co-Founder of Gensignia Life Sciences, Inc., a molecular diagnostics company focused on oncology using microRNA technology; Non-Executive Chairman and Founder of Accustem Sciences Limited; and founder of BioVitas Capital Ltd. Mr. Cerrone graduated from New York University's Stern School of Business with a master's degree in business administration (MBA).

Dr. Kunwar Shailubhai, Ph.D., M.B.A.

Dr. Kunwar Shalilubhai has served as Chief Executive Officer, Chief Scientific Officer and Executive Director of Tiziana since 2008 and a Director of teh Compnay since 2021. Since April, 2017, Dr. Shailubhai has served as Chief Executive Officer of Rasna Therapeutics, Inc. Dr. Shailubhai was a co-founder of Synergy Pharmaceuticals Inc. and served as Chief Scientific Officer from July 2008 to May 2017. From March 2004 until July 2008, Dr. Shailubhai served as Senior Vice President,Drug Discovery of Synergy, which at that time was a subsidiary of Callisto Pharmaceuticals, Inc. ("Synergy DE"). From May 2003 until March 2004, Dr.Shailubhai served as executive vice president, R&D of Synergy DE. From 2001 to April 2003, Dr. Shailubhai held the position of Vice President, DrugDiscovery at Synergy DE where he was chiefly responsible for the preclinical development of its GC-C agonist program for drugs to treat colon cancer andGI inflammation. Between 1993 and 2000, he was with Monsanto Company, serving as group leader of the cancer chemoprevention group. Dr. Shailubhai previously served as a senior staff fellow at the National Institutes of Health, and as an assistant professor at the University of Maryland. Dr. Shailubhai received his Ph.D. in microbiology in 1984 from the University of Baroda, India, and his MBA in 2001 from the University of Missouri, St. Louis.

Willy Simon

Willy Jules Simon has served as a Non-Executive Director of the company since November 2015. He is a banker and worked at Kredietbank N.V.and Citibank London before serving as an executive member of the Board of Generale Bank NL from 1997 to 1999 and as the chief executive of Fortis Investment Management from 1999 to 2002. He acted as chairman of Bank Oyens & van Eeghen from 2002 to 2004. He was chairman of AIM-tradedVelox3 plc (formerly 24/7 Gaming Group Holdings plc) until 2014 and had been a director of Playlogic Entertainment Inc., a Nasdaq OTC listed company. Willy Simon has been the chairman of Bever Holdings, a company listed in Amsterdam, since 2006 and Chairman of Ducat Maritime since 2015. He is also a non-executive director of OKYO Pharma Ltd plc and Tiziana Life Sciences Ltd.

John Brancaccio

John Brancaccio, a retired CPA, has served as a director of our company since July 2020. From April 2004 until May 2017, Mr. Brancaccio was the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. Mr. Brancaccio served as a director of Callisto Pharmaceuticals, Inc. from April 2004 until its merger with Synergy Pharmaceuticals, Inc. in January 2013 and has been a director of Tamir Biotechnology,Inc. (formerly Alfacell Corporation) since April 2004, as well as a director of Hepion Pharmaceuticals, Inc. since December 2013, Rasna Therapeutics, Inc.since September 2016, Cardiff Oncology, Inc. since December 2005 and Okyo Pharma Ltd plc since June 2020. Mr. Brancaccio served as a director of Synergy from July 2008 until April 2019.

Board of Directors

Our Board of Directors currently consists of five members consisting of the CEO and four Non-Executive Directors.

Board of Directors Meetings and Committees

Our Board of Directors has established an audit committee, a nomination committee and a remuneration committee. Each of these committees operates under formally delegated duties and responsibilities.

Audit Committee

The audit committee of the Board comprises John Brancaccio and Willy Simon. It is chaired by John Brancaccio, and is responsible for:

- monitoring the quality of internal controls and ensuring our financial performance is properly measured and reported on;
- consideration of the Directors' risk assessment and suggesting items for discussion at the full Board;
- receipt and review of reports from our management and auditors relating to the interim and annual accounts, including a review of accounting policies, accounting treatment and disclosures in the financial reports;
- consideration of the accounting and internal control systems in use throughout the Company and its subsidiaries; and
- overseeing our relationship with external auditors, including making recommendations to the Board as to the appointment or re-appointment of the external auditors, reviewing their terms of engagement, and monitoring the external auditors' independence, objectivity and effectiveness.

The Audit Committee meets not less than twice in each financial year and has unrestricted access to our auditors.
Our Board of Directors has determined that John Brancaccio is an "audit committee financial expert" as defined under section 5605(a)(2) of the Nasdaq Listing Rules.

In order to satisfy the independence criteria for audit committee members set forth in Rule 10A-3 under the Exchange Act, each member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the Board of Directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. We believe that the composition of our audit committee will meet the requirements for independence under current SEC rules and regulations.

Compensation Committee

The compensation committee of the Board comprises Willy Simon and John Brancaccio. It is chaired by Willy Simon, and is responsible for:

- the review of the performance of the Executive Directors;
- recommendations to the Board on matters relating to the remuneration and terms of service of the Executive Directors; and
- recommendations to the Board on proposals for the granting of share options and other equity incentives pursuant to any share option scheme or equity incentive scheme in operation from time to time.

In making their recommendations, the compensation Committee will have due regard to our shareholders' interests and our performance.

In order to satisfy the independence criteria for compensation Committee members set forth in Rule 10C-1 under the Exchange Act, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a remuneration committee member must be considered, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates. We believe the composition of our remuneration committee will meet the requirements for independence under current SEC rules and regulations.

Nomination Committee

The Nomination Committee of the Board comprises Gabriele Cerrone and Willy Simon. It is chaired by Gabriele Cerrone, and is responsible for:

- drawing up selection criteria and appointment procedures for Directors;
- recommending nominees for election to our Board of Directors and its corresponding committees;
- assessing the functioning of individual members of our Board of Directors and executive officers and reporting the results of such assessment to our Board of Directors; and
- developing corporate governance guidelines.

None of the members of our compensation committee is, or has ever been, an officer or employee of our company.

Code of Ethics

We have adopted a formal Code of Business Conduct and Ethics applicable to all Board members, officers and employees. Our Code of Business Conduct and Ethics can be found on our website at www.accustem.com. A copy of our Code of Business Conduct and Ethics may be obtained without charge upon written request to Secretary, AccuStem Sciences, Inc., 5 Penn Plaza, 19th Floor, #1954 New York, NY 10001. If we make any substantive amendments to our Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website (www.accustem.com) and/or in our public filings with the SEC.

Item 11. Executive Compensation

Summary Compensation Table

For the period from June 5, 2020 to December 31, 2020, and for the year ended December 31, 2021, we did not pay any cash compensation or benefits, such as pension, retirement or similar benefits, to our executive officer.

Consultancy Agreements

Keeren Shah

We entered into a consultancy agreement with Ms. Shah on March 1, 2021 to provide finance director services. Compensation under the consultancy agreement . This agreement entitles Ms. Shah to receive a base fee of $20,301 per annum. Ms. Shah may also be eligible to receive a bonus in an amount to be determined in our sole discretion.

Ms. Shah is not entitled to any fringe benefits. If Ms. Shah’s consultancy with the Company is terminated without cause, Ms. Shah will be entitled to a payment in lieu of notice to the equal to her basic salary for all or any remaining part of the relevant period of notice. The payment in lieu shall consist solely of her base fee for the relevant period and shall exclude any other entitlements or benefits.

Ms. Shah is also subject to a 6-month non-competition and non-solicitation covenant.

Annual Bonus

The Company currently has no annual bonus program.

Retirement Plan

The Company currently has no retirement plans.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information for the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options, as well as the exercise prices and expiration dates thereof, as of December 31, 2021

	Number of Securities Underlying Unexercised Options (#)		Option Exercise	Option Expiration
Name	**Exercisable**	**Unexercisable**	**Price ($)**	**Date**
Keeren Shah	762	—	0.42	8/1/2031

Director and Non-Employee Compensation Policy

The table above sets forth information regarding compensation earned by our non-employee Directors for the year ended December 31, 2021. During the period from June 5, 2020 to December 31, 2020 no compensation was earned.

	For the Year Ended December 31, 2021	
NAME	**FEES EARNED OR PAID IN CASH ($)**	**TOTAL($)**
Dr. Kunwar Shailubhai	—	—
Gabriele Cerrone	—	—
Willy Simon	4,166	4,166
John Brancaccio	4,166	4,166

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information with respect to the beneficial ownership of our common stock as of December 31, 2021 by:

- each of our Directors;
- each of our executive officers; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5 per cent. of our outstanding Common Stock.

Name and address of beneficial owner	Number of Ordinary Shares Beneficially Owned[1] Shares	%
Planwise Group Limited (2)	3,294,338	32.95%
Executive Officers and Directors [3]		
Gabriele Cerrone (3)	3,791,776	37.92%
Dr. Kunwar Shailubhai	20,250	*
Willy Simon	825	*
Keeran Shah	250	*

* Represents beneficial ownership of less than 1%. of our outstanding ordinary shares.

(1) “Percentage of Shares Beneficially Owned” is based on 9,999,132 common stock allotted as at December 31, 2021.

(2) Gabriele Cerrone, Chairman, is the beneficial owner of the entire issued share capital of Planwise Group Limited. Planwise Group Limited is incorporated in the British Virgin Islands with a registered address at Vistra Corporate Services Centre, Wickhams Cay II, Road Town, Tortola, VG1110, British Virgin Islands. Planwise is the registered owner of our initial subscriber share and will remain so for Companies Act purposes until the Demerger is completed; however, Planwise has neither voting power not disposal authority for the subscriber share.

(3) This includes shares held by Mr. Cerrone personally and shares held by Planwise Group Limited and Panetta Partners Limited (being entities in which Mr. Cerrone is considered to have a beneficial interest).

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Common stocksubject to options that are currently exercisable or exercisable within 60 days after December 31, 2021 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investment power with respect to all of the common stock beneficially owned by them, subject to community property laws, where applicable. The information in the table below is based on information known to us or ascertained by us from public filings made by the shareholders We have also set forth below information known to us regarding any significant change in the percentage ownership of our common stockby any major shareholders during the past three years. The major shareholders listed below do not have voting rights with respect to their common stock that are different from the voting rights of other holders of our common stock. To our knowledge there has been no significant change in the percentage ownership held by the major shareholders listed above in the last three years. We are not aware that the Company is directly owned or controlled by another corporation, any foreign government or any other natural or legal person (s) severally or jointly. We are not aware of any arrangement, the operation of which may result in a Change of Control of the Company.

Equity Compensation Plan Information

Summary Description of the 2021 Omnibus Equity Incentive Plan

Effective August 1, 2021 ("Adoption Date"), the Company adopted the 2021 Omnibus Equity Incentive Plan (the "Incentive Plan") to provide an additional incentive, strengthen the commitment, motivate to faithful and diligently perform responsibilities, attract and retain competent and dedicated individuals whose efforts will result in the long-term growth and profitability of the company, to selected employees, directors, and independent contractors of the company or its affiliates whose contributions are essential to the growth and success of the company. The Plan provides that the company may grant Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, and Other Stock-Based Awards. Any employee, director or consultant of the Company or any of its subsidiaries will be eligible to participate in the 2021 Plan. The number of shares of the Company Common Stock that will be reserved for issuance under the 2021 Plan will be 2,500,000. The Incentive Plan was transferred and effective on December 1, 2021 upon the Company's redomiciliation from the UK to the US.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Certain Relationships and Related Transactions

The following is a description of related party transactions we have entered into with the beneficial owners of 10%. or more of our common shares, which are our only voting securities, senior management and members of our Board of Directors, since June 5, 2020.

Agreements with Our Executive Officers and Directors

We have entered into an employment agreement with our Finance Director and Director compensation agreements with our Non-Executive Directors. See Item 11 – Executive Compensation These agreements contain customary provisions and representations, including confidentiality, non-competition and non-solicitation undertakings by the executive officer. However, the enforceability of the non-competition provisions may be limited under applicable law.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Director Independence

Our Board of Directors currently consists of four members, the Chairman and three Non-Executive Directors. Each Directors' term expires at the next annual general meeting of shareholders in 2022.

Under the Nasdaq Stock Market ("Nasdaq") listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. Our Board consults with our counsel to ensure that the Board's determinations are consistent with all relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Our Board has determined all of our directors, except for Ms. Blosser and Mr Cerrone, are "independent" directors, as defined under the rules of Nasdaq. In making such determination, the Board considered the relationships that each such non-employee director has with the Company and all other facts and circumstances that the Board deemed relevant in determining their independence, including the beneficial ownership of our common stock by each non-employee director. Our independent directors generally meet in executive session at each regularly scheduled Board meeting.

Item 14. Principal Accountant Fees and Services

Mazars LLP has been our auditor since our incorporation on June 5, 2020 and for registration statement filed on Form 20-F filed under International Financial Reporting Standards (IFRS); its address is Tower Bridge House, St Katharine's Way, London E1W 1DD, United Kingdom. Mazars is registered to perform audits in the U.K. by the Institute of Chartered Accountants in England and Wales and is a registered auditor with the PCAOB. In March 2022, the Audit Committee approved the appointment of Mazars USA LLP; its address 135 West 50th Street, New York 10020 as the Company's new independent registered public accounting firm. Mazars USA LLP will complete the audit of the Company under US GAAP for the periods ended December 31, 2021 and 2020.

Current Independent Registered Public Accounting Firm Fees

The Audit Committee works with our management in order to negotiate appropriate fees with its independent registered public accounting firm and is ultimately responsible for approving those fees. The following is a summary and description of fees for services provided by the independent registered public accounting firms in fiscal years 2021 and 2020. Other than as set forth below, no professional services were rendered or fees billed by Mazars USA LLP or Mazars LLP during fiscal years 2021 and 2020.

	2021	2020
Audit Fees*	$ 44,187	$ 41,195
Audit Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total	$ 44,187	$ 41,195

* Mazars USA LLP was not engaged until 2022, accordingly no fees were paid to Mazars USA LLP in 2020 or 2021. In 2022, we have been billed or expect to be billed approximately $85,000 for the audits of the years ended 2021 and 2020.

Item 15. Exhibits, Financial Statement Schedules

The financial statements, financial statement schedules, and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(1) Financial Statements

See "Index to the Consolidated Financial Statements" beginning on page F-1 of this report.

(2) Financial Statement Schedules

Financial statement schedules have been omitted because the required information is not present, not present in amounts sufficient to require submission of the schedules, or because the required information is provided in the financial statements or notes thereto.

(3) Exhibits

The exhibits required to be filed as part of this report are listed in the Exhibit Index attached hereto and are incorporated herein by reference.

3.1* **Amended and Restated Certificate of Incorporation of Accustem Sciences Inc.**

3.2* **Bylaws of Accustem Sciences Inc.**

10.1 Demerger Agreement between Tiziana Life Sciences PLC and AccuStem Sciences Limited dated October 5, 2020

10.2* **Supplemental Demerger Agreement between Tiziana Life Sciences PLC and AccuStem Sciences Limited dated October 30, 2020**

10.3* **License Agreement between Tiziana Life Sciences PLC and IEO/University of Milan dated June 24, 2014**

10.4* **Accustem Sciences Inc. 2021 Equity Incentive Plan**

21.1* **List of Subsidiaries**

23.1 Consent of Mazars USA LLP

31.1 Certification by Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended

31.2 Certification by Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended

32.1 Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2 Certification by Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

*** Previously filed.**

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on April 15, 2022.

ACCUSTEM SCIENCES, INC.
(Registrant)

/s/
Keeren Shah
Chief Financial Officer

In accordance with the Securities Exchange Act of 1934, this Report has been signed below on April 15, 2022 by the following persons on behalf of the Registrant and in the capacities indicated.

/s/ Wendy Blosser
Wendy Blosser
Chief Executive Officer and Director

/s/ Keeren Shah
Keeren Shah
Chief Financial Officer

/s/ Gabriele Cerrone
Gabriele Cerrone
Director

/s/ Dr. Kunwar Shailubhai
Dr. Kunwar Shailubhai
Director

/s/ Willy Simon
Willy Simon
Director

/s/ John Brancaccio
John Brancaccio
Director